

**NICNAS Response to Requests for
Variation of Draft Formaldehyde
Report**

1 November 2005

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Acronyms and Abbreviations

ACTU	Australian Council of Trade Unions
ADG Code	Australian Dangerous Goods Code
AFDA	Australian Funeral Directors Association
AIE	Australian Institute of Embalming
AMWU	Australian Manufacturing Workers Union
AS/NZS	Australian Standards/New Zealand Standards
ATSDR	Agency for Toxic Substances and Disease Registry (US)
AWPA	Australian Wood Panel Association
BCA	Building Code of Australia
CIIT	Chemical Industry Institute of Toxicology
CTFA	Cosmetic, Toiletry, and Fragrance Association
DIY	do it yourself
DNPH	2,4-dinitrophenyl-hydrazine
DPX	DNA protein cross-linking
EASE	Estimation and Assessment of Substance Exposure
EU	European Union
FCI	Formaldehyde Council Inc
FIDA	Funeral Industry Development Australia
GC/MS	Gas chromatography / mass spectrometry
GP	general practitioner
HPLC	high-performance liquid chromatography
IARC	International Agency for Research on Cancer
IPCS	International Programme on Chemical Safety
IRSST	Robert-Sauvé Workplace Health and Safety Research Institute
LC50	median lethal concentration
LD50	median lethal dose
LGA NSW	Local Government Association of NSW
LHMU	Liquor Hospitality & Miscellaneous Union
LLNA	Local Lymph Node Assay
LOEL	lowest-observed-effect level

MDF	Medium density fibreboard
MFE	Mortuary and Funeral Educators
MSDS	material safety data sheet
NCI	National Cancer Institute
NEPM	National Environmental Protection Measure
NHMRC	National Health and Medical Research Council
NICNAS	National Industrial Chemicals Notification and Assessment Scheme
NOEL	no-observed-effect level
NRC	National Research Council
NSW DEC	New South Wales Department of Environment & Conservation
NZ MfE	New Zealand Ministry for the Environment
NZ MoH	New Zealand Ministry of Health
OASCC	Office of Australian Safety and Compensation Council
ODREC	Occupational Dermatology Research & Education Centre
OES	Occupational exposure standard
OHS	occupational health and safety
PAA	Plywood Association of Australia
PEC	Priority Existing Chemical
PNEC	predicted-no-effect concentration
PPE	Personal protective equipment
QCU	Queensland Council of Unions
QLD DIR	Queensland Department of Industrial Relations
STEL	Short-term exposure limit
TNO	Netherlands Organisation for Applied Scientific Research
TWA	Time-weighted average
UK HSE	United Kingdom Health and Safety Executive
UN	United Nations
US EPA	United States Environmental Protection Agency
VNCI	Association of the Dutch Chemical Industry
VTHC	Victorian Trades Hall Council
WHO	World Health Organisation

Units

μg	microgram
μl	Microlitre
g	gram
m^3	cubic metre
ppb	Parts per billion
ppm	Parts per million

GENERAL COMMENTS

1 Variation requested by QLD DIR, Orica, AWWA/PAA

Change “formaldehyde” to “formaldehyde solution or formalin” for texts throughout the draft PEC report when dermal, gavage and intraperitoneal administration as exposures to formaldehyde are described.

Decision

Variation supported and amendments will be made where relevant.

2 Variation requested by QCU, AMWU, LHMU, ACTU, VTHC

i) The measures given should be consistent – ie the draft PEC report uses both ppm and ppb.

ii) Remove terms such as ‘considered to be’ (eg ‘formaldehyde is considered to be corrosive’ page v last paragraph, line 3) – either it is or it is not. If formaldehyde is corrosive then it is corrosive and the draft PEC report should be clearer.

Decision

Variations i) and ii) supported and text will be amended as appropriate.

OVERVIEW

3 Variation requested by Orica

Page v, line 1, delete “...and is biodegradable..”.

Decision

Variation supported.

4 Variation requested by FCI

i) Page v, 2nd paragraph, add following text after the 1st sentence:
“Formaldehyde is a ubiquitous and natural constituent of all living systems, from bacteria and fish to rodents and humans. As life evolved on the earth, formaldehyde became an important part of the process because it is one of the simplest biological forms of carbon. Even the most primitive organisms rely on formaldehyde as a one-carbon building block for the synthesis of more complex molecules. As a result of its importance in various metabolic processes, formaldehyde is naturally present in the human body with concentrations of approximately 1-2 parts per million (ppm) in the blood.”

ii) Similar statements should be included in following locations:

- page vi, 3rd paragraph,
- page vii, 4th paragraph;
- page 3, 1st paragraph;
- page 52-53, section 9.3, 2nd paragraph.

Decision

Variation i) partially supported. The following text will be added after the 1st sentence, paragraph 2:

“As a result of various metabolic processes, formaldehyde is naturally present in the human body at very low concentrations.”

Variation ii) not supported.

Comment

Variation i) - the proposed text is too detailed for the Overview.

Variation ii) - these details have been sufficiently summarised in the draft PEC report (section 2.1, 2nd paragraph and section 9).

5 Variation requested by Orica

Page v, paragraph 5: Delete the paragraph and replace with:

“Owing to its high water solubility, inhaled formaldehyde is readily absorbed in the regions of the upper respiratory tract with which it comes into contact. Its rapid metabolism and high reactivity with biological macromolecules confine formaldehyde to tissues of first contact and blood concentrations do not increase.”

Decision

Variation partially supported. The paragraph will be amended as:

“In humans and experimental animals, formaldehyde is readily absorbed by all exposure routes. When inhaled, it reacts rapidly at the site of contact and is quickly metabolised in the respiratory tissue.”

Comment

The 1st sentence suggested in the variation request does not cover all routes of exposure.

6 Variation requested by QCU, AMWU, LHMU, ACTU, VTHC

Page v, 7th paragraph, 2nd sentence, as this is a scientific document and the classification of a chemical as corrosive is a quantitative classification, the word "corrosive" needs to be deleted.

Decision

Variation supported.

7 Variation requested by QCU, AMWU, LHMU, ACTU, VTHC

i) Page vi, 2nd paragraph, the draft PEC report states ‘The available human and animal data indicate formaldehyde is unlikely to induce respiratory sensitisation’, but then continues: ‘Limited evidence indicates that formaldehyde may elicit a respiratory response in some very sensitive individuals with bronchial hyperactivity....’. Therefore, more accurate wording of the first sentence should be: ‘The available human and animal data indicate formaldehyde is unlikely to induce respiratory sensitisation in non-susceptible individuals.’

ii) the above comment also applies in other instances such as page vii, 5th paragraph, last sentence, ‘The risk of sensory irritation to the public is also considered to be low based...’ should be ‘The risk of sensory irritation to members of the public without predisposing sensitivity or allergy is also considered to be low based....’

Decision

Variations i) and ii) not supported.

Comment

Variation i) – the response in bronchial hyperactive persons is likely to be an irritant response, not sensitisation. Therefore it would be misleading to focus the discussion on sensitisation.

Variation ii) – sensory irritation is a not an allergic type of reaction. For clarity a definition of sensory irritation will be included in section 11.2.2, paragraph 2 of the draft PEC report:

“Sensory irritation is the result of the chemical stimulating the trigeminal nerve endings in the cornea and nasal mucosa, which evokes a stinging or burning sensation in the eyes and upper respiratory tract (nose and throat). This is a receptor mediated mode of action and occurs at relatively low concentrations. Sensory irritation is different to eye and skin irritation/corrosivity used for hazard classification (Section 12.2) and also different from the irritation leading to cytotoxicity, hyperplasia and nasal tumours (section 10.4.1). These latter examples are a result of physical damage to the cells, whereas sensory irritation is a nerve response.”

8 Variation requested by Orica

Page vi, paragraph 3, line 3, Insert “.....changes (cytotoxicity and hyperplasia)...”

Decision

Variation supported.

9 Variation requested by Orica

Page vi, paragraph 4, change to: “Formaldehyde in solution is clearly genotoxic in vitro, and gaseous formaldehyde may be genotoxic at respiratory tissue with which it first comes in contact. Overall, gaseous formaldehyde is”

Decision

Variation not supported.

Comment

Genotoxicity was seen in an oral study (Migliore et al, 1989), therefore, the current text is a more accurate reflection of the data.

10 Variation requested by FCI

Page vi, 7th paragraph, after 1st sentence, include “However, carcinogenic risk for formaldehyde is not expected at any reasonably anticipated exposure levels.”

Decision

Variation not supported.

Comment

At the current occupational exposure standard, the estimates indicate that carcinogenic risk is unacceptable.

11 Variation requested by Orica

Page vi, paragraph 8: insert after the 1st sentence the following:

“The following information nonetheless allows a confident conclusion to be made that at exposures relevant for humans it is very unlikely formaldehyde will cause reproductive effects. No adverse effects on fertility or parental toxicity were seen in a dietary study in minks. No systemic effects have been observed in animals and humans following repeated exposure to formaldehyde. This includes an absence of toxicity to male and female reproductive organs or sperm morphology in rodents. In addition blood formaldehyde levels do not increase in several species after exposure to high concentrations of formaldehyde making it very unlikely toxic effects distant from the site of first contact will occur.”

Decision

Variation partially supported. Text will be amended as follows:

“Based on animal and limited epidemiology data, formaldehyde is unlikely to cause reproductive and developmental effects at exposures relevant to humans.”

Comment

The proposed text is too detailed for the Overview.

12 Variation requested by Orica

Page vii, 1st paragraph, Delete sentence beginning “Formaldehyde is also” As it is a repetition of the sentence at the top pf page vi.

Decision

Variation supported.

13 Variation requested by Orica

Page vii, 2nd paragraph, Please amend this paragraph to include more background information relating to the development of the CIIT model.

Decision

Variation not supported.

Comment

Inclusion of more information on the CIIT model is too detailed for the ‘Overview’. However, more background information relating to the development of the CIIT model will be added in section 16.4.4.

14 Variation requested by FCI

Page vii, 2nd paragraph, 2nd sentence, amend it as: ‘This is a biologically-based, dose-response model that incorporates mechanistic data as well as data on respiratory tract physiology and regional air flow in animals and humans.’

Decision

Variation supported. The text will be amended as: “This is a biologically-based, dose-response model that incorporates mechanistic data. The model takes into account respiratory tract physiology and regional air flow in animals and humans.”

15 Variation requested by AWP/A/PAA

Page vii, 5th paragraph, replace the paragraph with following text:
“The predicted environmental concentrations of formaldehyde around wood and paper industry facilities emitting large amounts of formaldehyde are higher. These estimates are based on modeling and are estimates of concentrations at 100 meters from the facility. Assumptions required for modeling, result in some uncertainty in the estimated exposure levels but indicate locations where actual monitoring of formaldehyde levels should be undertaken. For residents living close to these types of facilities, the risk of respiratory tract cancer is negligible, and the risk of sensory irritation is low.”

Decision

Variation supported. This paragraph will read as:

“The predicted environmental concentrations of formaldehyde around wood and paper industry facilities emitting large amounts of formaldehyde are higher (119 ppb maximum 24-hour average levels). These estimates are based on modeling and are estimates of concentrations at 100 meters from the facility. Assumptions required for modeling, result in some uncertainty in the estimated exposure levels but indicate locations where actual monitoring of formaldehyde levels or site specific modeling should be undertaken.”

Consequential changes will be made accordingly throughout the draft PEC report where relevant.

Comment

Limited boundary data on formaldehyde levels around wood manufacturing plants were provided by the AWP/A/PAA during public comment stage. The data will be included in the draft PEC report.

16 Variation requested by AWP/A/PAA

Page vii, Paragraph 6, 4th and 5th sentences starting with “This is primarily due to...”, replace these sentences with “This is potentially due to the use of products that are high emitters of formaldehyde in these buildings, their higher usage of these materials, lower ventilation and /or small internal volume and the potential emission from combustion of gas used in cooking and refrigeration in these types of buildings. The later studies show much lower formaldehyde levels than the earlier ones, due to the development of much lower emitting wood panels over the past 8 years. The risk

of nasal cancer is negligible. There is a potential risk for sensory irritation if formaldehyde levels reach the LOEL level of 500ppb.”

Decision

Variation partially supported. The sentences will be amended as: “This is primarily due to the higher usage of products that emit formaldehyde in these buildings, relatively low ventilation rate and /or small internal volume, and other potential sources of formaldehyde such as from combustion of gas used in cooking and refrigeration. There is a potential risk of sensory irritation, but the risk of nasal cancer is estimated to be low.”

Comment

Due to very limited monitoring data, the later studies showing lower formaldehyde levels are not sufficient to draw any definite conclusions. Risk of sensory irritation to the general public should be interpreted by comparing the exposure levels with 80 ppb, the recommended indoor air guidance value, not 500ppb.

17 Variation requested by Orica

Page viii, 3rd and 7th paragraphs, replace last sentence with:

“Because formaldehyde solutions may induce skin sensitisation and even very low concentrations of formaldehyde in solution may elicit a dermatologic reaction in individuals who have been sensitised, dermal exposure should be minimised or prevented wherever possible.”

Decision

Variation supported.

18 Variation requested by Orica

Page ix, 2nd paragraph, Replace 2nd sentence with: “This should be revised in order to provide adequate protection against discomfort from sensory irritation and negligible cancer risk. It is”.

Decision

Variation not supported.

Comment

Based on the evaluation of human and animal data, whilst NICNAS believes the cancer risk is low and can be managed, it is not considered to be negligible.

Setting an acceptable level of risk is a policy decision. There is no policy statement, nationally or internationally, on what is an acceptable level of cancer risk.

NICNAS has classified formaldehyde as a cancer hazard and therefore there is a need to manage potential cancer risks. The current risk estimates are based on modelled data, using the CIIT model, and are not based on actual human cancer incidences. Although these estimates are considered to provide a better estimate of actual risk than, for example, the default approach of low-dose linear extrapolation, NICNAS notes that other models have estimated higher risks (from approximately 1×10^{-3} to 1×10^{-5}). Therefore, although NICNAS considers the risk of cancer to be low, we do

not consider that the strength of data nor the degree of certainty is sufficient to conclude that the cancer risk is negligible.

RECOMMENDATIONS

Preamble to recommendations for OHS

19 Variation requested by AWP/PA

Last dot point, replace with “In order to achieve lower occupational exposure limits the hierarchy of control process should be implemented.”

Decision

Variation partially supported. The following text will be added in the Preamble for Recommendations for Occupational Health and Safety (OHS) before the dot points:

“Preamble

It is best OHS practice to follow the hierarchy of controls when a risk assessment indicates a potential risk to workers’ health due to use of chemicals in the workplace.

The hierarchy of controls are:

1. Elimination
2. Substitution
3. Engineering controls
4. Safe Work Practices (Administrative practices)
5. Personal Protective Equipment

When deciding on the best way to control a risk, start at the top of the hierarchy of controls, i.e. investigate if the risk can be eliminated first, for example, by changing the way the work is done, or by using safer substances. This is the most effective way to control a hazard. If these methods are not possible, use engineering or administrative controls to reduce or minimise the risk. The final approach is to use appropriate personal protective equipment if the risk needs further control.

In addition, personal monitoring should be conducted where a workplace assessment indicates a potential risk to health due to exposure to hazardous chemicals, particularly, workplaces with possible high exposure to the chemical.

Based on the known hazards and risks of formaldehyde, best practice should be implemented to minimise or eliminate occupational exposure to formaldehyde.

Specifically for formaldehyde, it is noted that:...”

Comment

It is considered that reference to the hierarchy of controls is best placed in the Preamble as an introductory paragraph, as it applies to all workplaces and all chemicals. It is important to draw the hierarchy of controls to the attention of employers and employees.

20 Variation requested by QCU, AMWU, LHMU, ACTU, VTHC

Dot point 2, amend as: “Formaldehyde is a potent skin sensitiser. A no-effect level for skin sensitisation has not been identified, therefore, dermal exposure to formaldehyde products should be eliminated. Where this is not possible, dermal exposure should be minimised.”

Similarly, amend dot point 4 in the Preamble to ‘Recommendations for Public Health’

Decision

Variation supported. Both dot points will be amended as “Formaldehyde is a strong skin sensitiser.”

Comment

In addition, the inferred reference to hierarchy of controls will be brought forward to the Preamble to draw attention to general workplace control measures.

21 Variation requested by Orica

Dot point 2, amend as: “Formaldehyde in solution may induce skin sensitisation and even very low concentrations of formaldehyde in solution may elicit a dermatologic reaction in individuals who have been sensitised, therefore dermal exposure to formaldehyde solutions should be minimised or prevented.”

Similarly, amend dot point 4 in the Preamble to ‘Recommendations for Public Health’

Decision

Variation partially supported. Both dot points will be amended as “Formaldehyde is a strong skin sensitiser.”

Comment

In addition, the inferred reference to hierarchy of controls will be brought forward to the Preamble to draw attention to general workplace control measures.

Recommendation 1. Occupational hazard classification

22 Variation requested by QCU, AMWU, LHMU, ACTU, VTHC

i) Reclassify formaldehyde as a Category 1 carcinogen, as this recommendation goes against the available and recent international classifications. For Australia to have a different, lower, classification for a substance that is in common use is to provide Australian workers with less protection than their international counterparts.

Decision

Variation not supported.

Comment

Classification is a hazard based approach and does not consider risk. Formaldehyde has been classified as a cancer hazard (category 2) and therefore the potential risks need to be managed. Recommendations in this report, such as lowering the

occupational exposure standard and minimising the use of formaldehyde emitting products, will contribute to the management of the potential risks.

In order to classify a chemical as a category 1 carcinogen, there must be sufficient human evidence to establish a causal association between exposure to the chemical and cancer.

NICNAS concluded that the strength of the epidemiology data was not sufficient to establish a casual relationship between formaldehyde exposure and cancer. For nasopharyngeal cancers there are several epidemiological studies that show an increased risk, whereas other studies do not. Of the three recently published cohorts, only the NCI study (Hauptmann et al, 2004) showed an increased risk of nasopharyngeal cancers and this was associated with increased average exposure intensity and highest peak exposures. Coggon et al (2003) and Pinkerton et al (2004) did not observe an increased risk for nasopharyngeal cancers. In addition, Marsh and Youk (2005) reevaluated the data in the NCI study and concluded that there was little support for NCI's suggestion of a causal relationship between formaldehyde exposure and mortality from nasopharyngeal cancer. There are also concerns for an increased risk for formaldehyde-induced myeloid leukaemia, however, the available data are not considered sufficient to establish an association and there is currently no postulated mode of action to support such an effect. Therefore, it is considered that there is currently insufficient evidence to establish a causal association between human exposure and the development of cancer on the basis of epidemiological data.

NICNAS notes that there is ongoing follow-up for the NCI study, which is likely to be published in 2006. NICNAS believes it is important to review the NCI data and any other significant epidemiological date, when they become available. The following text will be added to section 19, Secondary Notification:

“NICNAS should re-evaluate the cancer hazard classification if and when any new significant epidemiology data becomes available.”

ii) S52 be applied in addition to those listed.

Decision

No variation required as S52 is already included in the sample MSDS recommended by NICNAS in Appendix 9. It is not NICNAS's practice to include safety phrases as part of the hazard classification.

iii) R43 also to be applied to mixtures with concentrations $\geq 0.1\%$ to $< 0.2\%$.

Decision

Variation not supported.

Comment

There is likely to be a threshold for skin sensitization and precautions can be taken to minimize the risk. In addition, the current specific value of 0.2% reflects Australia's alignment with EU classification. The EU's decision to set the concentration cut-off for skin sensitisation of formaldehyde at a level below the default value (ie 1%) indicates that the EU considered the potency of formaldehyde as a skin sensitiser.

Recommendation 2. National occupational exposure standard

23 Variation requested by QLD DIR

Replace this recommendation with: “It is recommended that OASCC does not change the current occupational exposure standard for formaldehyde which is 1ppm (1.2 mg/m³) 8hr TWA and 2ppm (2.5 mg/m³) STEL. Monitoring data collected from Australian workplaces indicate that it is technically feasible to keep exposures below these levels and workplaces should always strive to reduce levels below the Exposure Standard whenever this is technically feasible.”

Decision

Variation not supported.

Comment

It is NICNAS’s view that 1 ppm does not manage the cancer risk and notes that the LOEL for sensory irritation in humans is 0.5 ppm.

24 Variation requested by FCI, AWPA/PAA

The above organisations requested that the recommended occupational exposure standards be amended as 0.5 ppm 8h TWA and 1 ppm STEL. The reasons given are summarised below:

AWPA/PAA:

- makes no sense to require a TWA at a concentration lower than the lowest levels where symptoms might be expected to occur;
- Using the same reference data as used by NICNAS, a tripartite OHS organisation in Canada (IRSST) has come to the conclusion that an OES of less than 0.75ppm (either as a TWA or STEL) would make no difference at all to the health of wood panel workers exposed to formaldehyde;
- AWPA/PAA believes that a new OES of 0.5ppm TWA and 1.0ppm STEL would provide the necessary protection for all workers and prevent all known adverse health affects attributable to formaldehyde exposure.

FCI:

The weight of evidence, as primarily supported by the reviews by IRSST (2004), Bender (2002) and TNO (2005) demonstrate that the threshold for sensory irritation is in the range of 0.75 to 1 ppm, which is far greater than the proposed 0.3 ppm TWA and 0.6 ppm STEL. These reviews demonstrate that a TWA of 0.5 ppm and STEL of 1 ppm would be protective of human health.

Decision

Variation not supported.

Comment

Whilst NICNAS acknowledges that it is difficult to identify a definitive no observed effect level (NOEL) for sensory irritation, we has taken a cautionary approach and selected 0.5 ppm as the LOEL and added appropriate uncertainty factors to establish the recommended occupational exposure standard as 0.3 ppm. This value provides a

level that will not only manage the risk of sensory irritation, but also manage the cancer risk.

25 Variation requested by QCU, AMWU, LHMU, ACTU, VTHC

A specific recommendation to make workplace atmospheric monitoring mandatory is necessary.

Decision

Variation not supported.

Comment

This issue is already addressed in the hierarchy of controls which has been strengthened by adding relevant text in the Preamble. As stated, personal monitoring should be conducted where a workplace assessment indicates a potential risk. In addition, Recommendation 7 of the draft PEC report recommends that the state/territory authorities monitor industry compliance with this recommendation.

26 Variation requested by QCU, AMWU, LHMU, ACTU, VTHC

The draft PEC report and the relevant recommendations must take account of the fact that in many industries, the standard working day is no longer 8 hours.

Decision

Variation not supported.

Comment

This is a policy matter that should be addressed by OASCC. OASCC is responsible for providing policy advice on methodology for setting exposure standard for longer durations.

Recommendation 3. General workplace control measures

27 Variation requested by AWP/A/PAA

Recommendation 3 be removed and placed in the Overview section as a final paragraph of the section and amended text to incorporate the concept of risk and control measures:

“In the process of achieving occupational exposure limits employers should consider the application of the hierarchy of control to control these risks. First, identify and assess the risks, then decide if control is required. If it is decided on the best way to control (i.e. remove or reduce) them, by applying the Hierarchy of Controls (the wording below is largely adopted from the OASCC website document).

The Hierarchy of Controls = preferred order of control measures for OHS risks.

1. Elimination - controlling the hazard at source.
2. Substitution - eg. replacing one substance or activity with a less hazardous one.
3. Engineering - eg. installing guards on machinery
4. Administration - policies and procedures for safe work practices
5. Personal Protective Equipment - eg respirators, ear plugs.

When deciding on the best way to control a risk, start at the top of the hierarchy of controls, i.e. investigate if the risk can be eliminated first, for example by changing the way the work is done, or by using safer substances or equipment. This is the most effective way to control a hazard. If these methods are not possible, use engineering or administrative controls to reduce or minimise the risk. The final approach is to use appropriate personal protective equipment if the risk needs further control.”

Decision

Variation supported. The inferred reference to hierarchy of controls will be brought forward to the Preamble to draw attention to general workplace control measures.

28 Variation requested by FCI

Requests that all references to the elimination or substitution of formaldehyde be removed from the draft PEC report because the PEC recommendation is based on mistaken inference that there is no threshold for skin sensitisation.

Decision

Variation not supported.

Comment

According to Australian workplace legislations, the hierarchy of controls, including elimination or substitution, should be applied at the workplace where risks of health effects using formaldehyde exist. The draft PEC report has identified potential risks and made recommendations to manage those risks. The hierarchy of controls have been placed at the beginning of the Preamble for OHS recommendations to draw attention to them.

29 Variation requested by QCU, AMWU, LHMU, ACTU, VTHC

- i) ‘Elimination and substitution’ be separated into two sections,
- ii) ‘Process improvements’ be amended and re-ordered as follows: “In workplaces where elimination or substitution is not practicable, employers should seek further improvements in current workplace control measures and utilise best available technology to eliminate worker exposure to formaldehyde, wherever this is practicable. Control measures, such as enclosed systems or isolation, should be implemented at workplaces where heating processes are involved because formaldehyde gas can be released if heated to temperatures where the product (eg resin) decomposes. Where it is not practicable to eliminate worker exposure, measures should be taken to minimise it. For example, for core making, converting the hotbox process to warm box plus improved ventilation has resulted in significant reductions of workers’ exposure to formaldehyde.”

Decision

Variation i) and ii) partially supported.

The request to delineate elimination, substitution and process improvements will be addressed by including the Hierarchy of Controls in the Preamble to the

recommendations for Occupational Health and Safety (OHS). The following text will be added before the dot points:

“Preamble

It is best OHS practice to follow the hierarchy of controls when a risk assessment indicates a potential risk to workers’ health due to use of chemicals in the workplace.

The hierarchy of controls are:

1. Elimination
2. Substitution
3. Engineering controls
4. Safe Work Practices (Administrative practices)
5. Personal Protective Equipment

When deciding on the best way to control a risk, start at the top of the hierarchy of controls, i.e. investigate if the risk can be eliminated first, for example, by changing the way the work is done, or by using safer substances. This is the most effective way to control a hazard. If these methods are not possible, use engineering or administrative controls to reduce or minimise the risk. The final approach is to use appropriate personal protective equipment if the risk needs further control.

In addition, personal monitoring should be conducted where a workplace assessment indicates a potential risk to health due to exposure to hazardous chemicals, particularly, workplaces with possible high exposure to the chemical.

Based on the known hazards and risks of formaldehyde, best practice should be implemented to minimise or eliminate occupational exposure to formaldehyde.

Specifically for formaldehyde, it is noted that:...”

iii) dot point 4, under ‘Engineering controls and safe work practices’ be amended as ‘use of formaldehyde in sprays and aerosols should be eliminated.’

Decision

Variation supported. A new recommendation will be added and read as:

“Use of formaldehyde in spray and aerosol products should be voluntarily phased out by industry, and followed by a regulatory phase out.”

Recommendation 4. Hazard Communication

30 Variation requested by QCU, AMWU, LHMU, ACTU, VTHC

i) First dot point under MSDS: Add ‘and carcinogenicity’ to the end of this dot point.

ii) NICNAS recommends that industry ensure that all MSDSs and labels are compliant.

Decision

Variation i) supported.

Variation ii) supported. Recommendation 7 will be amended as: “It is recommended that, at an appropriate interval to allow industry to adopt the recommended workplace controls, including occupational exposure standard and MSDS and labels, state and territory occupational health and safety authorities review the compliance of workplaces, targeting industries with potential for high formaldehyde exposure, such as the embalming industry.”

31 Variation requested by LGA NSW

New text to be inserted after first paragraph: “It is recommended that introduction of product labelling occur that identifies low-emission wood products, similar to the German Blue Angel scheme, to enable consumers to choose safer products, should these be available.”

Also, the possibility of the introduction of product labelling targeted at the public identifying the hazards associated with formaldehyde and the steps that should be taken to reduce the risk, such as those set out in Recommendation 12, could also be considered.

Decision

Variation partially supported. The following text will be added in Recommendation 14 as the 2nd paragraph:

“To facilitate consumer choice and use of safer products, low formaldehyde emitting products should be labelled accordingly.”

Comment

For noting, there is a product labelling system on formaldehyde emissions for Australian manufactured wood products (see the draft PEC report page 200-202 and Appendix 11 and 12). In addition, the Standards Australia formaldehyde emission standards include requirements for product labelling.

Recommendation 5. Specific recommendations for the embalming industry

32 Variation requested by QCU, AMWU, LHMU, ACTU, VTHC

i) Dot points 1 & 2: The development of any materials, guidelines, etc must be done in consultation with organisations representing the workers (unions) and should be co-ordinated through either OASCC or one of the state/territory Authorities to be the ‘lead’ agency. Same request to Dot points 1 & 2 of Recommendation 6 ‘Specific recommendations for the forensic/hospital mortuaries and pathology laboratories’.

Decision

Variation supported. The dot point 1&2 for Recommendation 5 will be combined to one dot point and read as:

“It is recommended that the Australian Funeral Directors Association (AFDA) and the Australian Institute of Embalming (AIE), together with the registered training organisations for embalming industry, the Funeral Industry Development Australia (FIDA) and Mortuary and Funeral Educators (MFE), use the information in this report to 1) update information on formaldehyde in their training materials for embalmers; 2) develop a specific guideline for controlling non-infectious hazards such as hazardous

chemicals (including formaldehyde) for embalmers. The development of any material and guidelines should be in consultation with relevant stakeholders such as state/territory authorities and organisations representing the workers.”

Similar amendment will be made for Recommendation 6, dot point 1&2.

ii) Dot point 3, 2nd paragraph, Many workplaces have no atmospheric monitoring in place. NICNAS recommendations must make atmospheric monitoring mandatory and clearly advise this.

Decision

Variation not supported.

Comment

This issue is already addressed in the hierarchy of controls which has been strengthened by adding relevant text in the Preamble. As stated, personal monitoring should be conducted where a workplace assessment indicates a potential risk. In addition, Recommendation 7 of the draft PEC report recommends that the state/territory authorities monitor industry compliance with this recommendation.

iii) Dot point 4: NICNAS must involve the relevant union/s in the preparation of all Safety Information Sheets recommended in the draft PEC report.

Decision

Variation supported.

33 Variation requested by QLD DIR

3rd dot point, the paragraph starting with “Embalmers should pay particular attention to...”, insert “In particular, nitrile and neoprene gloves should be used as latex gloves are less effective over prolonged periods”

Decision

Variation not supported.

Comment

It is not customary for NICNAS to include for recommendations on appropriate glove types, as the choice of type of PPE needs to take a number of factors into consideration such as permeability of other ingredients in the product. However, this issue will be covered in the Safety Information Sheets to be developed. QLD DIR will be consulted in this process.

Recommendation 7. Compliance with state and territory legislation

34 Variation requested by QCU, AMWU, LHMU, ACTU, VTHC

An appropriate time interval must be specified, for example, ‘not more than 12 months’.

Decision

Variation partially supported. Recommendation 2 (to OASCC), 1st paragraph, last sentence, will be amended as:

“OASCC should consider the recommended exposure standard as a matter of priority, with a view to declaration within 12 months.”

Comment

The determination of an implementation interval will depend on several factors, such as the time taken for OASCC and subsequently the state/territory authorities to adopt the NICNAS recommendations, and possible consultations between state/territory authorities and industry on an agreed interval. While noting all the above, NICNAS supports prompt action be taken to lower the occupational exposure standard.

Recommendation 10. Standards Australia

35 Variation requested by LGA NSW

This recommendation should read as: “It is recommended that Standards Australia adopt and/or develop a standard(s) for mobile and relocatable buildings which include guidance on ventilation and use of press wood products that meet revised Australian Standards in regard to formaldehyde emissions limits. The revised Standard(s) should be incorporated into the Building Codes of Australia.

Decision

Variation for insert ‘revised’ in the 1st sentence supported.

Variation for incorporating the revised standard(s) into the Building Codes of Australia not supported.

Comment

Incorporation of relevant Australian standards into BCA was looked into by NICNAS during formulation of the recommendations. However, the majority of the state/territory legislations that call up the BCA do not include mobile homes and relocatable buildings in their definition of a “building” (refer to the draft PEC report, 1st paragraph, page 195). Therefore, this recommendation would not achieve the desired outcome. However, NICNAS sees the value in the variation request and offers to meet with LGA NSW to progress this issue.

36 Variation requested by AWP/A/PAA

Add a recommendation to Standards Australia to re-develop the Australian standard for testing formaldehyde in indoor air, AS 2365.6-1995, Methods for the Sampling and Analysis of Indoor Air. Method 6:Determination of Formaldehyde - Impinger Sampling- Chromotropic Acid Method due to interferences and quality related problems using Chromotropic Acid.

Decision

Variation supported. The recommendation now reads as: “It is recommended that Standards Australia adopt and/or develop applicable method(s) for the sampling and analysis of formaldehyde in indoor air.”

Recommendation 11. Mobile home and relocatable building manufacturers

37 Variation requested by QCU, AMWU, LHMU, ACTU, VTHC

Add a dot point: “Provide information to purchasers of mobile homes and relocatable buildings on the extent of wood products used in the manufacture of the home/building and whether or not low formaldehyde materials were used.”

Decision

Variation partially supported. The following text will be added in Recommendation 14 as the 2nd paragraph:

“To facilitate consumer choice and use of safer products, low formaldehyde emitting products should be labelled accordingly.”

38 Variation requested by AWPAA/PAA

Delete dot point one and replace it with: “design the structure to ensure that the indoor air guidance value of 80ppb is not exceeded.”

Decision

Variation supported.

39 Variation requested by Ausco Building Systems Pty Ltd.

i) Prior to concluding specific recommendations for relocatable buildings, conduct further research to understand causal factors and to illustrate the sensitivity or magnitudes due to differing building materials, fit out or provisioning (furniture, cooking equipment etc.).

ii) If this recommendation is retained, please quantify dots 3 and 4. For example, is typical acrylic paint over MDF beneficial and to what extent? Is polyester coating over plywood beneficial and to what extent? What time periods are involved in “venting” of buildings and to what extent does this effect results?

Decision

Variations i) and ii) not supported.

Comment

Variation i) - there are some studies investigating the causal factors (see the draft PEC report, page 128). Further research in monitoring indoor air formaldehyde in mobile buildings is recommended in the Recommendation 13. This information will assist industry in determining what risk management options should be implemented.

Variation ii) – Contributors to indoor air levels are multifactorial and qualitative measures to address indoor air levels have been noted. However, it is not possible to quantitatively answer the questions posed due to lack of data. Should industry have this data, NICNAS would quantify the issue. Research by industry to quantify these issues would assist industry to meet the indoor air guidance value of 80 ppb for this type of buildings.

Recommendation 12. Residents/occupants of mobile homes and relocatable buildings

40 Variation requested by AWPAA/PAA

Delete dot point 4 and replace with “where possible/practicable, ensure that furniture and fittings are manufactured from materials that are low formaldehyde emitters.”

Decision

Variation supported.

Recommendation 14. Communication

41 Variation requested by QCU, AMWU, LHMU, ACTU, VTHC

This information should also cover relocatable classrooms and be provided to state and private education departments/offices and teaching unions. Unions should also be used to distribute this information.

Decision

Variation supported.

Recommendation 16. Utilisation of health hazard assessment

42 Variation requested by QCU, AMWU, LHMU, ACTU, VTHC

OASCC must also be included as a government agency that should use the NICNAS health hazard assessment.

Decision

Variation not supported.

Comment

Recommendation 16 is directed to government agencies responsible for public health. Specific recommendations for OHS have already been made to OASCC (recommendations 1 and 2) in the draft PEC report.

Preamble to Recommendations for environmental protection

43 Variation requested by NSW DEC

2nd dot point, should read “Formaldehyde is a hazardous air pollutant otherwise known as an ‘air toxic’.”

Decision

Variation supported.

44 Variation requested by Orica

Last dot point, change to: “The preliminary dispersion modelling of formaldehyde around wood and paper industry facilities emitting large amounts of formaldehyde indicates specific additional investigations are warranted and procurement of better data for modelling purposes.”

Decision

Variation supported. The sentence will read as: “The preliminary dispersion modelling of formaldehyde around wood and paper industry facilities emitting large amounts of formaldehyde indicates that the ambient air formaldehyde levels could be higher than the NEPM investigation level of 40 ppb.”

Consequently, Recommendation 18 will be amended as:

“To ensure the estimated environmental concentrations of formaldehyde around wood and paper facilities are representative, it is recommended that high emitters of formaldehyde in wood and paper industries conduct monitoring and/or undertake site specific modelling.”

Recommendation 18. Formaldehyde emission investigation

45 Variation requested by NSW DEC

Recommendation 18 suggests that investigations be undertaken to determine environmental concentrations of formaldehyde at the perimeters of high emitters such as the wood and paper industries.

NSW DEC has found that is normally more effective to require stack emission monitoring along with modelling to estimate ground level concentrations at the maximally exposed individual or the perimeter or a facility.

Decision

Variation supported. Recommendation 18 will be amended as:

“To ensure the estimated environmental concentrations of formaldehyde around wood and paper facilities are representative, it is recommended that high emitters of formaldehyde in wood and paper industries conduct monitoring and/or undertake site specific modelling.”

In addition, the following wording will be added in section 13.1.4, 3rd paragraph: “This may be accomplished either by monitoring at the perimeter or by stack emission monitoring along with modelling to estimate ground level concentrations at the maximally exposed individual or the perimeter of a facility. The latter approach should be adopted for facilities where the local topography would indicate that the maximum exposure is likely to occur outside the perimeter of the facility.”

NEW RECOMMENDATIONS REQUESTED

New Recommendation 1

46 Variation requested by LGA NSW

Phasing out of uses of formaldehyde that pose a public health risk, such as use in cosmetics and in mobile and relocatable homes.

Decision

Variation not supported.

Comment

It should be noted that the control measures recommended by NICNAS, such as indoor air guidance value of 80 ppb and encouraging use of low formaldehyde emission products, all aim to control public exposure to formaldehyde and are considered adequate. Also the recommendation for controlling risks from cosmetics uses includes prohibition of use of formaldehyde and paraformaldehyde in spray cosmetics products. This report and its recommendations will be forwarded to NDPSC to adopt appropriate measures to control risks.

New Recommendation 2

47 Variation requested by LGA NSW

If phase out uses of formaldehyde that pose a public health risk is not possible, i) lower permissible levels for formaldehyde in building and home products should be recommended in order to meet best practice international levels (European EI Standard; Japanese Building Standards Laws), and these be incorporated into Australian Standards and ii) the Building Codes of Australia.

Decision

Variation i) supported. The following text will be added to Recommendation 10: "It is recommended that Standards Australia adopt international testing and labelling practices for assessing emissions of formaldehyde from materials, which allow for testing to low emission levels as provided in other countries such as Japan."

Variation ii) not supported.

Comment

Variation request ii) - Incorporation of relevant Australian standards into BCA was looked into by NICNAS during formulation of the recommendations. However, the majority of the state/territory legislations that call up the BCA do not include mobile homes and relocatable buildings in their definition of a "building" (refer to the draft PEC report, 1st paragraph, page 195). Therefore, this recommendation would not achieve the desired outcome. However, NICNAS sees the value in the variation request and offers to meet with LGA NSW to progress this issue.

TABLE OF CONTENTS

48 Variation requested by Orica

Add titles to the Appendices.

Decision

Variation supported.

CHAPTER 4 CHEMICAL IDENTITY AND COMPOSITION

49 Variation requested by QLD DIR

Page 8, section 4.2 'Registry numbers', UN number, change (>25%) to "not less than 25%", which means greater than or equal to 25% (see ADG Code).

Decision

Variation supported.

CHAPTER 5 PHYSICAL AND CHEMICAL PROPERTIES

50 Variation requested by Merck

Page 12, table 5.1, the heading is wrong. They should read "...property of formaldehyde and 37% formaldehyde solution". Similarly towards the bottom, at flashpoint for formalin, it should read: "(for 37% formaldehyde solution without methanol or with 15% methanol)".

Decision

Variation supported.

CHAPTER 6 METHODS OF DETECTION

51 Variation requested by AWPAA/PAA

Section 6.2.3, 1st paragraph, the use of chromotropic acid is problematic, suffering from a number of interferences and quality related problems. Suitable methods are active collection onto DNPH and analysed via HPLC or GC/MS or similar. The use of passive sampling techniques should be fully verified by active means before adoption. Examples of suitable active methods are US EPA TO 5 and TO11.

Decision

Variation supported. Page 15, from 4th paragraph, text will be replaced with: "In addition, several other methods of detection for measuring ambient air formaldehyde levels are available including:

- United States Environmental Protection Agency (USEPA) Method TO5, (*title and reference*);
- USEPA Method TO11, (*title and reference*).

The recent NEPM document (NEPC, 2004) recommended use of two other USEPA testing methods:

- USEPA Compendium Method TO-11A (reference). *Determination of Formaldehyde in Ambient Air Using Adsorbent Cartridge Followed by High Performance Liquid Chromatography* (active sampling methodology);
- USEPA Compendium Method TO15, (reference, as an alternative method) *Determination of Volatile Organic Compounds (VOCs) in Air Using Specially-Prepared Canisters and Analysed by Gas Chromatography/Mass Spectrometry (GC/MS).*”

6.2.3 Indoor air

Formaldehyde concentrations in indoor air can be measured by either active or passive sampling using a sampler followed by analysis using a number of methods. The use of passive sampling techniques should be fully verified by active means.

Currently, there is an Australian Standard for testing formaldehyde in indoor air, AS 2365.6-1995, *Methods for the Sampling and Analysis of Indoor Air. Method 6: Determination of Formaldehyde –Impinger Sampling- Chromotropic Acid Method* (Standards Australia, 1995). However, there are problems with use of chromotropic acid due to interferences and quality related issues. There are more suitable methods including active collection onto DNPH which are analysed via HPLC or GC/MS or equivalent analytical methods. The USEPA methods discussed above (TO5, TO11, TO11A, and TO15) are also suitable for measuring indoor air formaldehyde.

There are a number of ISO documents on indoor air formaldehyde testing. They are:

- ISO 16000-2 Indoor air - part 2: Sampling strategy for formaldehyde (*reference*).
- ISO 16000-3 Indoor air - part 3: Determination of formaldehyde & other carbonyl compounds - Active sampling method. (based on USEPA method TO-11A) (*reference*).
- ISO 16000-4 Indoor air - part 4: Determination of formaldehyde - Diffusive sampling method. (i.e. passive sampling with badges) (*reference*).

The Standards Australia Indoor Air Committee advised that the Committee will be considering these ISO methods along with other methods such as the USEPA methods when determining suitable testing methods for indoor air formaldehyde in the future.

Methodology for the simultaneous sampling of a number of indoor airborne aldehydes including formaldehyde is also available. A recent paper investigated detecting indoor air formaldehyde using a direct reading device (Suzuki, 2003). However, this method has certain limitations and serves mainly for screening purposes.”

CHAPTER 7 USES

52 Variation requested by AWP/PA

Page 24, 1st paragraph, last sentence, request either delete it or replace it with “If the amount of free formaldehyde in a resin needs to be ascertained the MSDS, the product specification or the manufacturer should be consulted.”

Decision

Variation supported and the sentence will be deleted. Consequential statements in the draft PEC report will also be deleted.

53 Variation requested by NSW DEC

Page 36, 3rd paragraph, last sentence, change “destroys” to “to destroy”.

Decision

Variation supported.

54 Variation requested by an individual

Fragrances from some air fresheners (eg. ‘Airwick’) react with ozone and produce formaldehyde that causes skin rash to some individuals. This should be included in the draft PEC report and more research should be done.

Decision

Variation not supported.

Comment

Airwick manufacturer has confirmed that this product series do not contain formaldehyde. They contain fragrances that may react with ozone to produce formaldehyde in air. However, the draft PEC report concludes that gaseous formaldehyde is unlikely to cause skin sensitisation or skin irritation.

CHAPTER 8 ENVIRONMENTAL RELEASE, FATE AND EFFECTS

55 Variation requested by Orica

Page 45, paragraph 5,

i) add at the beginning of paragraph:

“The daytime half life of formaldehyde in ambient air is generally short.”

ii) Add at the end of the paragraph:

“In the absence of NO₂ the half life of formaldehyde is approximately 50 minutes during daytime but in the presence of NO₂ is only about 35 minutes (Bufalini et al. 1972).”

Decision

Variation i) supported.

Variation ii) supported and following text will be added at the end of the paragraph 1, on page 46:

“During the day, reaction with hydroxyl radicals is an important removal process of formaldehyde when their concentration is high. At night, reaction with nitrate radicals is an important (although slower) removal process, particularly in polluted urban areas where the concentration of nitrate radicals is high (Atkinson, 2000; IPCS, 2002). In the absence of nitrogen dioxide, the half-life of formaldehyde is approximately 50 min during the daytime; in the presence of nitrogen dioxide, this drops to about 35 min (IPCS, 1989). In winter on clear days, residence times of formaldehyde will be longer than in summer because the intensity of sunlight is lower.”

Comment

The Bufalini reference has not been obtained but it is cited in the IPCS report (1989).

56 Variation requested by NSW DEC

Page 48, 3rd paragraph, This paragraph discusses some no observed effect concentration data from non-standard tests on fish. It appears that this data has been misquoted. The data referred to in this paragraph is for the chemical which is not a mixture of formaldehyde and other chemicals but actually a chemical in its own right as indicated by its unique CAS No 2749-70-4. This paragraph should be deleted from the draft PEC report and any use of the data in estimating PNECs should be corrected as the data is in no way relevant to the assessment of formaldehyde.

Decision

Variation supported. The paragraph dealing with the toxicity of dibenzyl acetal formaldehyde will be removed.

57 Variation requested by NSW DEC

Page 50, 1st paragraph of section 8.3.3, it is noted that formaldehyde is used in aquaculture for the control of parasites and infections. This appears to be a use pattern that needs to be assessed.

Decision

Variation not supported.

Comment

Use of formaldehyde in aquaculture is regulated by the Australian Pesticides and Veterinary Medicines Authority (APVMA) and therefore falls outside the scope of this review and was not assessed by NICNAS.

CHAPTER 9-11 HEALTH EFFECTS

The NICNAS decisions on variation requests to ‘Health Effects’ sections are arranged in the following order:

- Sensory irritation
- Skin sensitisation
- Carcinogenicity
- Other effects

Sensory Irritation

58 Variation requested by Orica and AWPA/PAA

Define the term ‘sensory irritation’, include the mode of action and define how the effect is different from other irritant effects.

Decision

Variation supported. The following definition will be included in section 11.2.2, paragraph 2:

“Sensory irritation is the result of the chemical stimulating the trigeminal nerve endings in the cornea and nasal mucosa, which evokes a stinging or burning sensation in the eyes and upper respiratory tract (nose and throat). This is a receptor mediated mode of action and occurs at relatively low concentrations. Sensory irritation is different to eye and skin irritation/corrosivity used for hazard classification (Section 12.2) and also different from the irritation leading to cytotoxicity, hyperplasia and nasal tumours (section 10.4.1). These latter examples are a result of physical damage to the cells, whereas sensory irritation is a nerve response.”

In addition, the first 2 sentences in section 12.2 will be deleted, because they are not relevant to the hazard classification for irritation.

59 Variation requested by Orica, QLD DIR and FCI

The above organisations request that the LOEL for sensory irritation should be replaced by

- i) a ‘NOEL of 0.5 ppm for the majority of the population’ (Orica)
- ii) a ‘NOEL of 0.75 to 1.0 ppm’ (FCI)
- iii) a LOEL of 1 ppm (QLD DIR)

The reasons given are summarised below:

Orica:

The draft PEC report concludes that some individuals begin to sense irritation from 0.5 ppm but the response rate is often similar to controls. In every other field of toxicology an exposure concentration that did not cause effects different from controls would be taken as the no observed effect level (NOEL). The “very unreliable” and “limited evidence” of “some people” reporting sensory irritation at 0.25 ppm is not empirical data supporting effects lower than 0.5 ppm. For the majority of the population, 0.5 ppm represents a no effect level for sensory irritation.

FCI:

The weight of evidence, supported by the reviews by IRSST (a Quebec organisation), Bender (2002) and a review by the Association of the Dutch Chemical Industry (VNCI) for the Netherlands Organisation for Applied Scientific Research (TNO) to

evaluate the Dutch criteria document for the formaldehyde exposure standard (note: report not submitted to NICNAS), support a NOEL of 0.75 ppm to 1.0 ppm.

QLD DIR:

All studies cited in Table 11.1 had limitations: Anderson & Mulhave did not have a control group; exposure was short in Bender's study, and in other studies there were not controls or irritation did not appear until 1 ppm.

Decision

Variations i), ii) and iii) not supported. For clarity text will be amended on Page 76, 6th paragraph as follows:

“A definitive no observed effect level (NOEL) for sensory irritation is difficult to identify because sensory irritation is a subjective effect. This is compounded by the fact that the available data for formaldehyde are not sufficiently robust for low exposures. The data from chamber ...”.

Consequential changes will be made accordingly throughout the draft PEC report, ie. deleting references to ‘no reliable NOEL for sensory irritation’.

Comment

Sensory irritation relies on subjective reporting of symptoms and therefore it is difficult to identify a definitive NOEL. In addition, the sensory irritation data for formaldehyde at low doses are not robust. The chamber studies which have indicated eye irritation effects (the most sensitive effect) at or below 0.5 ppm are Anderson and Molhave (1983) and Bender et al (1983). The Kulle studies report no eye irritation at 0.5 ppm, the only dose tested below 1.0 ppm. The other chamber studies have either not tested at concentrations below 1.0 ppm or do not provide data for the individual exposure concentrations. It is acknowledged that the data are limited and all studies have limitations. The sensory irritation effects at the lower doses should not be dismissed on the basis of a significant number of controls also report symptoms. Based on the weight of evidence, it is concluded that there are some individuals who will experience sensory irritation at 0.5 ppm. Therefore, 0.5 ppm should be considered a LOEL and not an NOEL.

NICNAS has used a cautionary approach and appropriate uncertainty factors based on the evidence of mode of action and available data for sensory irritation. In addition, NICNAS notes that this level will also provide adequate risk management for nasal cancers. Therefore, NICNAS does not support a NOEL at or above 0.5 ppm or a LOEL higher than 0.5 ppm.

Several references to ‘no reliable NOEL’ will be deleted because this statement can be seen as misleading. It is not that there is no NOEL, but a NOEL is not easily defined for a subjective effect.

60 Variation requested by Orica

Request to include following text after paragraph 2 on page 69:

“With effective airborne concentrations sensory eye irritation by formaldehyde has rapid onset but the intensity of effect does not significantly increase with longer exposures (Sauder et al. 1987, Yang et al 2001). This is in accord with the theoretical

considerations of sensory irritation where the intensity of response is dependent on the final concentration of the substance in the fluid bathing tissue. This is determined by the air:water partition coefficient and for very water soluble substances like formaldehyde steady state is rapidly achieved (Hau et al 1999). Given that the intensity of sensory irritation is dependent upon the concentration of formaldehyde in biological fluid bathing the eye and conjunctiva, it follows that once steady state between mucosa and/or tear film is reached with any given air concentration of formaldehyde then the maximum, or near maximum, level of sensory irritation is also reached.”

Also include following text and table on Sauder et al (1987) study:

“Table 11.1 reproduces data from Sauder et al (1987) for sensory irritation by 3 ppm formaldehyde. There is rapid onset of effect (at 2 minute exposure there was approximately 80% of the intensity observed at 3 hr) but, within experimental limitations, the effect at 2 minutes was not markedly different than at later evaluation times.

Table 11.1

Table 11.1: Time course of sensory eye irritation by formaldehyde ^a.

	Group mean symptom scores ^b						
	0 min	2 min	15 min	30 min	60 min	120 min	180 min
A. Clean air	0.0	0.0	0.11	0.11	0.11	0.22	0.0
B. 3ppm HCHO	0.0	1.0	1.0	1.11	1.33	1.44	1.33
B – A	0.0	1.0	0.89	1.0	1.22	1.22	1.33

^a Data from Sauder et al (1987).

^b Mean irritation score of 9 subjects on scale 0 = none, 1 = mild (present but not annoying), 2 = Mild/Moderate, 3 = Moderate (annoying) and 5 = severe (debilitating).

Decision

Variation partially supported. The following text will be included after the 3rd paragraph, page 69:

“Sensory irritation due to exposure to formaldehyde has rapid onset (Sauder et al. 1987, Yang et al 2001) and the intensity of effect does not appear to significantly increase with longer exposures (Sauder et al. 1987). This is in accord with the theoretical considerations of sensory irritation where the intensity of response is dependent on the concentration of the substance and not the duration of exposure.”

Comment

It is difficult to justify the level of detail and conclusions drawn from Sauder et al. study by Orica with such a limited number of subjects (9) for a subjective endpoint.

61 Variation requested by Orica

Additional text and changes to be made to page 69 and Table 11.1

i) Delete the statement: ‘The exposure duration limits the usefulness of this study’ for the Bender et al (1983), Weber-Tschopp et al (1977) and Yange et al (2001) entries.’

Decision

Variation supported.

ii) Bender et al (1983):

- Include in comment section ‘Subjects were selected on historical complaints of eye irritation by formaldehyde’.
- Include the following text on page 69, before the last sentence of paragraph 4: “Similarly Bender et al (1983) selected volunteers who had historically reported eye irritation to formaldehyde. Exposures were for 6 minutes at 0. 0.35, 0.56, 0.7 and 0.9 ppm and the incidence for eye irritation respectively 39, 42, 54, 57, 60 and 74%.”

Decision

Variation partially supported. Additional data will be included in the Table as follows:

- Eye irritation response at 0 ppm changed from 0% to ‘not applicable’
- Comment field: Eye irritation measured as percentage of subjects whose response time to formaldehyde, was less than response time to clean air. Individuals were known to respond to formaldehyde (previously reporting eye irritation) and served as own controls.

Comment

With additional text in Table 11.1, the study is now adequately summarised. The study design does not enable a percentage to be reported at 0 ppm, hence the table has been amended to say ‘not applicable’.

iii) Harving et al (1990):

- Add following text on page 69, paragraph 2: “Exposures of asthmatics to 0.6 and 0.1 ppm produced sensory irritation that could not be distinguished from background levels [of 0.006 ppm].”
- In Table in Comment field include sentence: ‘Details for sensory irritation conclusions by the authors not provided.’

Decision

Variation partially supported.

- Summary of study will be amended to: ‘In a study by Harving et al (1990), 15 asthmatics were exposed in a chamber for 90 minutes to 0.007, 0.1 and 0.7 ppm formaldehyde. There was no association between the subjects’ ratings of asthmatic symptoms and increasing exposure.’
- Sentence will be added to Comment field in Table: “Sensory irritation was not investigated in this study.”

Comment

Harving did not include any information on sensory irritation, only ‘asthmatic symptoms’.

iv) Anderson and Molhave (1983)

Include following in Table:

- These results are not published in a peer reviewed journal and data for zero formaldehyde exposure are not reported.
-more ‘discomfort’ than 0.4 ppm indicating acclimatization occurred.
- Formaldehyde concentrations are 1 hour averages and exposures 5 hrs.

- Even at the highest concentration the subjects highest average discomfort rating never exceeded the middle of the ‘slight discomfort’ range.
- There were no carry-over symptoms.
- Change the heading to: Subjective eye irritation &/or dry nose/throat.

Decision

Variation partially supported.

- Additional text will be included in Comment field: ‘Individuals were asked to rate their level of discomfort. At all exposure levels, the highest individual rating was ‘discomfort’, which was the middle rating. The average rating for all exposures was ‘slight discomfort’. Following the first 2 hours exposure, 0.25 ppm caused more ‘discomfort’ than 0.4 ppm. The results are not published in a peer reviewed journal.’
- Heading will be changed as requested.

Comment

There is data on 0 exposure in Figure 7.

v) Kulle et al studies:

Amend text to ‘*between 0.5 – 1 ppm*’

Decision

Variation not supported.

Comment

Author states that ‘estimated thresholds were, 0.5 – 1.0 ppm formaldehyde for eye irritation’ as reported in the draft PEC report.

vi) Reed and Frigas (1984):

Provide data in same format as other studies.

Decision

Variation not supported. For clarity, text will be amended as follows:

“Eye, nose and throat irritation: Self-reports of eye, nose and throat irritation occurred as frequently with clean air [symptoms were not reported for the different exposure levels (0.1, 1.0 and 3.0 ppm)].”

Comment

Changes sought have not been made because the results for the different exposure concentrations were not reported.

vii) Page 69, paragraph 4, line 7: Start new paragraph and delete the word ‘Similarly.’

Decision

Variation supported.

62 Variation requested by Orica

Page 76, paragraph 5:

i) Line 3, insert: “...concluded that with community and workplace studies it is not ..
“

ii) Line 10, insert: “...is not unusual when people think they are exposed to formaldehyde but are not). At levels

Decision

Variations i) and ii) not supported.

Comment

Variation i) - chamber studies have also contributed to this conclusion

Variation ii) - the issue of controls reporting effects is adequately covered in the draft PEC report.

63 Variation requested by Orica

Page 76, last paragraph, change to:

“Therefore, although formaldehyde is a known sensory irritant for the human eye and upper respiratory tract, the available data and subjective nature of sensory irritation do not allow identification of an unconditional no observed effect level (NOEL) for the entire population.”

Decision

Variation partially supported. The text will be amended as follows:

“Therefore, although formaldehyde is a known upper respiratory tract irritant in humans, the limitations of the available data and subjective nature of sensory irritation do not allow identification of a definitive no observed effect level (NOEL).”

Consequential changes will be made accordingly throughout the draft PEC report.

Skin Sensitisation

64 Variation requested by Orica

“no effect levels (NOELs) for skin sensitisation have not been identified for formaldehyde” is misleading as it implies NOELs were sought but not found. Thresholds for both the induction and elicitation phases of skin sensitisation are well known. But a precise threshold for sensitisation by formalin has not been elucidated by the studies.

Decision

Variation supported. Following text will replace the paragraph in section 16.4.3:

“Several animal and human studies (Marzulli & Maibach, 1974; Jordan et al, 1979; Hilton et al, 1996; Hilton et al, 1998) have been conducted to induce and/or elicit a skin sensitisation response for the purpose of hazard identification. These studies were conducted at doses to elicit a response and not designed to identify a threshold.

There is growing consensus that thresholds can be identified for skin sensitisers [Kimber et al., 1999; 2001; Boukhman & Maibach, 2001; EU Working Group on Sensitisation (ECBI/13/02 Add.1), http://ecb.jrc.it/classlab/1302a1_Report.doc]. At

present, which tests are the most appropriate to identify a threshold have not been agreed upon.

Work is also underway to categorise skin sensitisers according to their potency. For example, the EU Expert Group on Sensitisation (ECBI/81/02, 2002, http://ecb.jrc.it/classlab/8102_Sensitisation_1102_report.doc.) proposed three categories of skin sensitisers (extreme, strong, moderate) based on a range of sensitisation tests (LLNA, Bueller, and human data). The Expert Group categorised formaldehyde as a strong skin sensitiser.”

Also, the following text will be added to section 11.3.1 (after 2nd paragraph, on page 78):

“A number of human studies were conducted to induce (Marzulli & Maibach, 1974) and elicit skin sensitisation in sensitised individuals [Marzulli & Maibach, 1973 cited in the IPCS review (1989); Jordan et al, 1979; Hilton et al, 1998]. The IPCS report (2002) concluded that the concentration of formaldehyde likely to elicit contact dermatitis reactions in hypersensitive individuals may be as low as 30 mg/L (0.003%). ATSDR (1999) concluded that allergic skin responses in sensitised individuals exposure to concentrations below 0.25 to 0.05% formaldehyde in solution are rare.”

Statements of “a no-effect level has not been identified” and “dose-response data for skin sensitisation is not available.” will be deleted in the draft PEC report.

65 Variation requested by CTFA, FCI

The above organisations have requested that the statement ‘a no effect level for skin sensitisation has not been identified’ is incorrect. The reasons given are summarised below:

CTFA:

“No effect levels (NOELs) for skin sensitisation have not been identified for formaldehyde” is not correct as two studies, Marzulli & Maibach (1974) and Jordan et al (1979) investigated thresholds for induction and elicitation of sensitisation to formalin.

FCI:

There is a skin sensitisation for formaldehyde in both normal and sensitised individuals. 1% solutions are not expected to be irritating to most people. FCI referenced ATSDR report (1999) and studies by Marzulli & Maibach (1974) and Jordan et al (1979) as evidence.

Decision

Variation not supported.

Comment

It is not correct to say that thresholds for induction and elicitation of skin sensitisation by dermal exposure of formaldehyde solutions have been identified, based on the following text which will replace the paragraph in section 16.4.3:

“Several animal and human studies (Marzulli & Maibach, 1974; Jordan et al, 1979; Hilton et al, 1996; Hilton et al, 1998) have been conducted to induce and/or elicit a

skin sensitisation response for the purpose of hazard identification. These studies were conducted at doses to elicit a response and not designed to identify a threshold.

There is growing consensus that thresholds can be identified for skin sensitisers [Kimber et al., 1999; 2001; Boukhman & Maibach, 2001; EU Working Group on Sensitisation (ECBI/13/02 Add.1), http://ecb.jrc.it/classlab/1302a1_Report.doc]. At present, which tests are the most appropriate to identify a threshold have not been agreed upon.”

66 Variation requested by Orica

A review of formaldehyde animal and human skin sensitisation be conducted and the appropriate contextual information provided to allow transparency for the conclusions/recommendations in the draft PEC report. Also provide the experimental details of all the sensitisation tests cited in the draft PEC report.

Decision

Variation not supported. For clarity the following text will be added to the beginning of section 10 and 11:

“This chapter is a brief summary of the health effects of formaldehyde that is mainly based on the IPCS report (IPCS, 2002) prepared by the Health Canada, ATSDR (1999) and SIAR (2002). Articles published post 1998 are summarised in this chapter.”

Comment

NICNAS is committed to using international peer-reviewed documents in its chemical assessment activities. Skin sensitisation is a well-known end point for formaldehyde and has been discussed in a number of peer reviewed documents (IPCS, 2002; IPCS, 1989; ATSDR, 1999 etc.). Therefore, NICNAS did not include details in the draft PEC report, but will include reference where this data is publicly available.

In addition, as noted by Orica’s submission, these studies were not designed to identify a threshold. Therefore, there would be little value in including more information on these studies.

67 Variation requested by Orica

The reasons why formaldehyde is described as being a “potent” skin sensitiser are not provided. The descriptor “potent” should be deleted.

Decision

Variation partially supported. ‘Potent skin sensitiser’ will be replaced by ‘strong skin sensitiser’ throughout the draft PEC report and information on EU’s recent work on potency of skin sensitisers will be included in section 16.4.3.

68 Variation requested by Orica

Skin sensitisation is only induced via dermal exposure of formaldehyde solutions, not via inhalation of formaldehyde gas.

Decision

Variation supported. Following text will be added after the 1st paragraph in section 10.3.1 for animal data:

“There is no evidence in inhalation studies with rats, mice, hamsters or monkeys that for formaldehyde gas induces skin sensitisation.”

Following text will be added after the last paragraph of section 11.3.1 for human data:
“No human data to suggest that exposure to formaldehyde gas causes skin sensitisation.”

69 Variation requested by Orica

Page 56, Section 10.3.1, 1st sentence: Change to “Skin sensitisation studies with gaseous formaldehyde were not located however the skin sensitisation potential of formaldehyde solutions has been”

Decision

Variation supported.

70 Variation requested by ODREC

page 77, Table 11.2, delete ‘%’ in column heading.

Decision

Variation supported.

71 Variation requested by Orica

Section 17.2.2, page 181, 4th paragraph, line 3, Please insert: “.are not available. However IPCS (1989) indicate skin sensitisation is induced only by direct skin contact with formaldehyde solutions in concentrations higher than 20g/litre (2%). Although concentrations”.

Decision

Variation not supported.

Comment

NICNAS checked the IPCS (1989) report and confirmed the above statement in the Summary (section 1.8). However, this statement is not supported by the data in chapter 8 (animal data) and 9 (human data) of the IPCS report. In addition, in section 9.2.4 (page 142) of the IPCS report, it stated “Formaldehyde is a known sensitiser for the skin (DFG, 1987), but no thresholds for induction of dermal, respiratory tract, or systemic sensitisation have been reliably determined.”

Carcinogenicity

72 Variation requested by Department of Health, WA

Include recent publications on carcinogenicity and formaldehyde: Franks (August 2005); Cole and Axten (November 2004); Heck and Casanova (November 2004); Marsh and Youk (March, 2005), Collins (2004).

Decision

Variation supported. A summary of references relevant to carcinogenicity will be included, as this is a critical endpoint.

73 Variation requested by QCU, VTHC, AMWU, ACTU, LHMU

Include a discussion on the IARC report with respect to nasopharyngeal cancers.

Decision

Variation supported. The following text will be added to paragraph 2, page 112: "IARC has concluded that there was 'sufficient' evidence in humans to establish a causal association between formaldehyde exposure and nasopharyngeal cancer. IARC's conclusion was principally based on the statistically significant findings of increased nasopharyngeal cancer mortality in the recent update of the NCI cohort (Hauptmann et al, 2004), together with similar findings in 2 other cohorts (Hayes et al, 1990 and Hansen & Olsen, 1995) and an elevated risk in five of seven case-control studies. IARC stated that it was "improbable that all of the positive findings...could be explained by bias or by unrecognised confounding effects".

74 Variation requested by QCU, VTHC, AMWU, ACTU, LHMU

Request that the draft PEC report acknowledge the conclusion of the IARC Working Group that there is 'strong' but not sufficient evidence for a causal association between leukaemia and occupational exposure to formaldehyde.

Decision

Variation supported. The following text will replace the last sentence in section 12.6: "In relation to leukaemia, IARC concluded that there was 'strong but not sufficient' evidence of a causal association between leukaemia and occupational exposure to formaldehyde. They noted that earlier findings of increased mortality in cohorts of professional workers (such as embalmers and pathologists) had recently been supported by an increased incidence of leukaemia in 2 of 3 recent updates of large cohorts of industrial workers. IARC noted that a mechanism for leukaemia induction could not be identified, and this tempered their interpretation of the epidemiological evidence."

The differences in NICNAS and IARC carcinogenicity classifications for formaldehyde are principally due to what is considered to be the strength of evidence for causality. However, it is important to note that NICNAS has classified formaldehyde as a cancer hazard and therefore there is a potential cancer risk and this risk need to be managed.

For consistency in the draft PEC report page 102, 2nd paragraph, last sentence will be amended as: ‘Overall, it is considered that the epidemiology data are insufficient to establish a causal association between occupational exposure to formaldehyde and leukaemia.’

75 Variation requested by FCI

Include the following sentence at following locations:

- page vi, paragraph 5;
- page 92, paragraph 2;
- page 272, 2nd paragraph.

“A study from the US National Cancer Institute (NCI) (Hauptmann et al. 2004) serves as the principal basis for this finding and efforts are now underway by NCI and the study authors to update the findings of this study.”

Decision

Variation partially supported. The following text will be included in section 11.6.1, at the end of ‘Summary’:

“Follow-up of the National Cancer Institute cohort continues and the findings should assist in further elucidating the strength of the association between formaldehyde and nasopharyngeal cancer.”

Comment

The Hauptmann 2004 study is one of several epidemiology studies that have indicated an increased risk.

76 Variation requested by Orica

Several requests for variation for section 16.1 were submitted that are consequential to other variations sought by Orica.

Decision

Text will be amended in accordance with other decisions. In addition, paragraph 3, 1st sentence will be amended as follows: “Eye and respiratory irritation have been reported in human epidemiology and chamber studies.”

Other Health Effects

Kinetic and Metabolism

77 Variation requested by Orica

Page 52, paragraph 1, first sentence, contextual information to enable interpretation of the data in Section 9.1 needs to be provided. Delete the 1st sentence and replace with: “Owing to its high water solubility, inhaled formaldehyde is readily absorbed in the regions of the upper respiratory tract with which it comes into contact. Its rapid metabolism and high reactivity with biological macromolecules confine formaldehyde to tissues of first contact and blood concentrations do not increase.”

Decision

Variation not supported.

Comment

This issue is discussed in section 9.2 'Distribution'.

78 Variation requested by Orica

Page 52, paragraph 1, delete last sentence. "Data on elimination of total radioactivity following exposure of rats to ¹⁴C – formaldehyde suggest complete absorption of formaldehyde may occur following inhalation exposure".

Decision

Variation supported.

Acute toxicity**79 Variation requested by Orica**

Page 54, Section 10.1,

i) Table 10.1 indicates that the dermal LD50 in rabbits is the same as the oral LD50 in guinea pigs and both are less than the oral LD50 in rats. It is unusual that dermal LD50's are the same as or less than oral LD50's. Some discussion should be provided since it does not fit the reactivity or general toxicological profile of formaldehyde, and is highly unlikely to be the result of species susceptibility.

Decision

Variation not supported.

Comment

The figures in Table 10.1 are from publicly available reviews, therefore, provision of references is considered sufficient. This level of detail does not add significantly to the findings of the draft PEC report.

ii) provide the species for which clinical signs were observed and interpret the information by providing a probable cause of death. Also include in life description of non-lethal effects.

Decision

Variation not supported.

Comment

This level of detail does not add significantly to the findings of the draft PEC report.

iii) The references for Smyth et al (1941) and Lewis & Tatken (1980) are not in the bibliography. Please supply them.

Decision

Variation supported.

iv) Add the formalin concentrations to the table for each of the data for oral and dermal which may explain the dermal/oral relativity anomaly.

Decision

Variation not supported.

Comment

This level of detail does not add significantly to the findings of the draft PEC report. Also, the references are from publicly available reviews.

Skin Irritation

80 Variation requested by Orica

Page 54, Section 10.2.1, insert at the beginning of the Section: “Skin and eye irritation studies in animals for gaseous formaldehyde were not found” as all the data cited in this section is for formalin. There are no data for gaseous formaldehyde.

Decision

Variation partially supported. Following text will be added:

“Skin irritation studies in animals for gaseous formaldehyde were not found.”

Comment

Eye irritation was observed in some acute inhalation studies in animals (see Table 2-1 in the ATSDR report, 1999).

81 Variation requested by Orica

Page 68, section 11.2.1, insert the following text as a separate paragraph at beginning of this section.

“Acute controlled exposure studies of volunteers exposed to airborne formaldehyde at concentrations up to 3 ppm have not found increased reporting of skin irritation symptoms (ATSDR 1999).”

Decision

Variation supported. The suggested text will be added as a separate paragraph after the 1st paragraph.

82 Variation requested by AWWA/PAA

In the draft PEC report there are several comments regarding the skin irritation effects of formaldehyde. Formaldehyde gas is not a skin irritant. Formaldehyde solution (formalin) is considered a skin irritant and the draft PEC report should be modified to recognise this distinction.

Decision

Variation supported. Relevant parts of the draft PEC report will be amended accordingly.

Respiratory Sensitisation

83 Variation requested by QLD DIR

Page 80, Section 11.3.2, 'Respiratory', Near top of page 80. Change 32 (38 µg/m³) to 32 ppb (38 µg/m³).

Decision

Variation supported.

Repeated dose toxicity

84 Variation requested by Orica

Page 57, paragraph 6, Insert the following after the last sentence:

“Furthermore it is the concentration rather than the total dose (i.e. concentration x time of exposure) that determines the severity of this cytotoxicity (IPCS, 1989).”

Decision

Variation partially supported. The following text will be added:

“Some studies (Wilmer et al., 1986; 1987) indicated that it is the concentration rather than the total dose (i.e. concentration x time of exposure) that determines the severity of this cytotoxicity.”

Comment

The IPCS review (1989) described this finding of the studies by Wilmer et al. (1986, 1987), but did not draw such a conclusion.

85 Variation requested by Orica

- i) Section 10.4.2, provide experimental details of the cited studies, especially the concentration of formaldehyde in the administered vehicle;
- ii) Section 10.4.2, page 60, paragraph 2, include more information on the dog study;
- iii) Section 10.4.3, line 5: “.....100µl of a 10%, 2% or 1% formaldehyde solution
.....”

Decision

Variation i) - supported. Text will be amended where data are available.

Variations ii) and iii) supported.

Genotoxicity

86 Variation requested by Orica

Page 60, Section 10.5.1, state at the beginning of the section whether any of the in vitro genotoxicity tests were conducted with gaseous formaldehyde.

Decision

Variation supported. Under section 10.5.1, 1st paragraph, 1st sentence will be changed to: “A large number of studies have been conducted in vitro with either gaseous or aqueous formaldehyde and a wide variety of endpoints assessed.”

87 Variation requested by Orica

Page 61, Section 10.5.2, 2nd paragraph, line 3, 5, 7, include the strength of formaldehyde solutions tested.

Decision

Variation supported.

Reproductive and Developmental Toxicity

88 Variation requested by Orica

Page 65, Section 10.7, paragraph 2: It is suspected that the data in this paragraph is incorrectly referenced to Ward et al. 1984. Please check.

Decision

Variation supported. The reference will be checked and amended accordingly.

89 Variation requested by Orica

Page 66, paragraph 2: For all the studies cited, formaldehyde administration was i.p. therefore, it was via formaldehyde solutions. Also the strength of the formaldehyde solution should be provided because acute peritoneal irritation/ulceration and associated stress may account for some of the observations cited.

Decision

Variation not supported.

Comment

Due to the questionable relevance of these studies (ip administration is not a relevant normal route of human exposure) and because these studies are not pivotal to the risk assessment and final recommendations, reporting in such detail is not considered warranted.

90 Variation requested by Orica

Page 171, 1st paragraph, insert following text after the 1st sentence to replace the next 2 sentences at lines 2-6:

“The following information nonetheless allows a confident conclusion to be made that at exposures relevant for humans it is very unlikely formaldehyde will cause reproductive effects. No adverse effects on fertility or parental toxicity were seen in a dietary study in minks. No systemic effects have been observed in animals and humans following repeated exposure to formaldehyde. This includes an absence of toxicity to male and female reproductive organs or sperm morphology in rodents. In addition blood formaldehyde levels do not increase in several species after exposure to high concentrations of formaldehyde making it very unlikely toxic effects distant from the site of first contact will occur.”

Decision

Variation partially supported. Replace the 1st sentence with: “The available data indicate that at exposures relevant to humans, it is unlikely that formaldehyde will cause reproductive and developmental effects.” Also the last 2 sentences of this paragraph will be deleted.

CHAPTER 12 HAZARD CLASSIFICATION**91 Variation requested by Orica**

Page 108, section 12.2, paragraph 3, line 2: Insert “.....of a direct irritant effect....”.

Decision

Variation supported.

92 Variation requested by Orica

Page 108, section 12.2, paragraph 4, replace the 1st sentence with following text: “There are sufficient data to show gaseous formaldehyde is a sensory irritant to the eye and upper respiratory tract, and in high concentrations a direct irritant to nasal tissue. Formaldehyde solutions are irritants to the eye and in concentrations $\geq 0.5\%$ are skin irritants.”

Decision

Variation not supported. However, for clarity reference to sensory irritation in this section on hazard classification will be deleted.

93 Variation requested by Orica

Page 109, 1st paragraph: Insert following text after the last sentence: “Similarly the UK Health and Safety Executive (HSE 1997) concluded the data for formaldehyde does not meet the EU Criteria for classification as a respiratory sensitiser”.

Decision

Variation not supported.

Comment

This section is an independent evaluation of the available data by NICNAS against the Australian classification criteria. As such it is not relevant to list classification outcomes of other countries.

94 Variation requested by Orica

Page 109, Section 12.4,

i) Line 5: Insert “..... symptoms of sensory irritation...”

ii) Line 11: Insert reference: “...study (reference) the weight.....”

Decision

variations i) and ii) supported.

95 Variation requested by Orica

Page 109, Section 12.5, 1st paragraph, 1st sentence, Request “circulating (was ‘peripheral’ in the draft PEC report) lymphocytes” be deleted and “sites of first contact” be changed to “upper respiratory tract sites of first contact” because there is no information relating to genotoxic effects at all the sites of first contact (e.g. the eye and skin) and circulating lymphocytes are not regarded as a site of first contact.

Decision

Variation supported. The sentence will be amended as:

“Overall, epidemiology data from occupational studies investigating cytogenetic effects in nasal and buccal cells are suggestive of formaldehyde having a weak localised genotoxic activity, while the evidence for a systemic activity, including peripheral lymphocytes, is equivocal.”

96 Variation requested by FCI

Delete recommendation that the current classification of carcinogen category 3 be changed to category 2. This request is based on the fact that, as the draft PEC report concludes, carcinogenic risk for formaldehyde is not expected at any reasonably anticipated exposure levels.

FCI requested several other variations to the text that are consequential to the classification decision.

Decision

Variation not supported.

Comment

Several epidemiological studies have shown an increased risk of nasopharyngeal cancer, however, it is noted that other studies have not shown an increased risk. There is also clear evidence from inhalation studies of nasal squamous cell carcinomas in the rat, though not the mouse and hamster. The postulated mode of action for these tumours is considered likely to be relevant to humans. Therefore, based on the available nasopharyngeal cancer data, formaldehyde should be regarded as if it may be carcinogenic to humans following inhalation exposure (category 2). There are also concerns for an increased risk for formaldehyde-induced myeloid leukaemia, however, the available data are not considered sufficient to establish an association and there is currently no postulated mode of action to support such an effect.

CHAPTER 13 ENVIRONMENTAL EXPOSURE

97 Variation requested by NSW DEC

Page 114-119, Section 13.1.1, data from the National Pollutant Inventory has been used to assess the contribution of various industries to the 15% of emissions of

formaldehyde to air that come from industrial point sources. This data has inherent uncertainties resulting from the method of collection. The possible impacts of the data gaps should be discussed more thoroughly in the text.

Decision

Variation supported. The summary section, 2nd paragraph on page 119 will be modified as follows to highlight the uncertainties:

“The maximum annual average and maximum 24-hour average PECs for each industry category are shown in Table 13.1. It should be remembered that these PEC predictions have been derived using data from the NPI database in which most of the data has been estimated. As such, the PEC predictions should be interpreted cautiously owing to uncertainties in the initial release estimates. In addition, not all industrial sources report to the NPI.”

98 Variation requested by NSW DEC

Page 119-120, Section 13.1.2, as part of the Air Toxics NEPM each state is conducting a desktop analysis of potential emissions of each of the listed air toxics including formaldehyde. This work is scheduled for completion soon. Given the importance of diffuse source emissions in evaluating formaldehyde impacts on the environment it would be worth waiting until this information becomes available before finalising this report.

NSW DEC indicates that this work is raising the potential of aircraft and shipping to contribute significantly more to ambient levels of formaldehyde than currently estimated in the NPI aggregate emissions.

Decision

Variation not supported.

Comment

As a result of the stage at which the assessment is at and the associated statutory time frames it is not possible to hold finalising the PEC report to include this potentially valuable data. Should the data raise significant new issues then these can be considered under secondary notification provisions.

99 Variation requested by AWP/A/PAA

i) Page 125, 6th paragraph, 2nd sentence, change to: “Recently measured concentrations in occupied caravans ranged from 8 ppb to 175 ppb (average 29 ppb). In this study 2 of the 60 caravans investigated exceeded the NHMRC recommended level of 100 ppb, however no examination or reason for these variations are given.”

ii) Page 125, 6th paragraph, 3rd sentence, change to: “Although the data is limited, concentrations appear to have decreased from the levels detected in previous surveys (McPhail, 1991; Dingle et al., 1992). Significant work has been undertaken by Australian manufacturers of pressed wood products since the 1990’s to reduce the emissions from their products. As a result the data from earlier studies may not be relevant today. These improvements have been attributed to changes in resin

technology and improved manufacturing controls for product emissions (Houghton et al., 2002)

Decision

Variation i) supported. Text will be amended as: “Recently measured concentrations in occupied caravans ranged from 8 ppb to 175 ppb (average 29 ppb). In this study 2 of the 60 caravans investigated exceeded 100 ppb (Dingle et al., 2000). The same study found that in unoccupied caravans, the formaldehyde levels ranged from 10 ppb to 855 ppb (average 100 ppb).”

Variation ii) partially supported. The sentence remains as is, but data (two bar charts showing the changes of formaldehyde emission levels over the last 15 years and testing methodology) were provided by the AWWPA which demonstrate reductions in formaldehyde emissions from Australian made pressed wood products. This data will be added in section 18.2.2, page 201, at the end of 2nd paragraph as follows: “Details of the reduction in formaldehyde emission levels of some Australian made wood panel products over the last 15 years were provided by the AWWPA (see Appendix 12).”

Comment

The pressed wood products used in manufacturing mobile buildings are not all Australian made products. According to information provided by industry, the majority of the plywood used in mobile buildings is imported (refer to the draft PEC report, page 127, 2nd paragraph). The formaldehyde emission status of imported pressed wood products is unknown (refer to page 201, 3rd paragraph). However, the data on reduction in formaldehyde emissions from Australian made wood panel products are useful information and will be included in the draft PEC report.

100 Variation requested by AWWPA/PAA

Page 126, 4th paragraph, 1st sentence, amend to: “Among pressed wood products, particleboard and MDF that are bonded with formaldehyde based resins have been recognised as emitters of formaldehyde (Kelly, 1999; Brown, 2002).”

Decision

Variation supported.

CHAPTER 14 PUBLIC EXPOSURE

101 Variation requested by Orica

Page 137, paragraph 1, second sentence, the subject matter is the concentration of formaldehyde in mainstream smoke, therefore, the units should be mass per volume of smoke.

Decision

Variation not supported.

Comment

NICNAS acknowledges that the concentration would be mass per volume but we have checked the NHMRC report (1997) and can confirm that they report the unit for the concentration of formaldehyde in mainstream smoke as $\mu\text{g}/\text{cigarette}$.

102 Variation requested by Orica

Page 137, paragraph 2, the exposure calculation in this paragraph is ambiguous and should consider a number of aspects and should be recalculated (suggested recalculation was provided) or deleted.

Decision

Variation supported and the paragraph will be deleted.

CHAPTER 15 OCCUPATIONAL EXPOSURE**103 Variation requested by QLD DIR**

Page 140, section 15.3 'Formaldehyde manufacture', Last paragraph, last sentence, "Respiratory protection equipment is available and used where...". Recent experience while auditing a Major Hazard Facility manufacturing formaldehyde and associated resins is that this respiratory equipment was available and used, but not maintained.

Decision

Variation supported. The information will be added in section 18.3.2, page 132, 5th paragraph, under 'PPE' as: "Respiratory protection equipment needs to be maintained".

104 Variation requested by QLD DIR

Page 163, Table 15.8a, sampling method column, the 7th entry, replace "2-hydrxymethyl" with "2-hydroxymethyl".

Decision

Variation supported.

105 Variation requested by QCU, AMWU, LHMU, ACTU, VTHC

There is no consideration in the draft PEC report that there will be workplaces where exposures are well above the (current) exposure standard and therefore the carcinogenic risk is present and the level unknown, such as mortuaries and pathology laboratories. The draft PEC report should be varied to reflect this.

Decision

Variation not supported.

Comment

Workplaces where exposures may be above the current exposure standard were indicated in the tables summarising workplace monitoring data. Together with the CIIT occupational cancer risk estimation results, the recommendations 5 and 6 for the above mentioned specific industries have been made to address the management of the cancer risks.

106 Variation requested by QCU, AMWU, LHMU, ACTU, VTHC

There are no reports on the potential for exposures or measurements taken from the foundry industry, even though there is reference to that industry on page xi.

Decision

No variation required as there is information in Table 15.4. Although the data are limited, it supports the statement on page xi.

107 Variation requested by QCU, AMWU, LHMU, ACTU, VTHC

Potential source of exposure from spills or leaks during importation is not mentioned.

Decision

No variation required as this issue was addressed in section 15.4, 3rd paragraph on page 141 of the draft PEC report.

108 Variation requested by QCU, AMWU, LHMU, ACTU, VTHC

Whilst the text in section 15.6.1 notes that DIY applications may expose people to airborne formaldehyde there is no discussion regarding the potential exposure standards for this group.

Decision

Variation not supported.

Comment

The proposed indoor air guidance value and the occupational exposure standards will be protective both the general public and workers. In addition, it is difficult to estimate potential exposure when use patterns vary considerably. However, it is anticipated that exposure would be intermittent.

109 Variation requested by QLD DIR

In chapter 15, some tabulated occupational air monitoring data applies to analytical methodology involving short sampling periods intended to represent activities/locations which are of substantial duration. The reported single sample results are likely to involve a large coefficient of variation, such that the reported result may be misleading or not useful for the purpose of reviewing exposure standards.

Decision

Variation partially supported. A paragraph will be added in section 15.2 'Methodology for assessing occupational exposure', after the 1st paragraph, as follows:

“A reasonable amount of air monitoring data was received during the assessment, especially for formaldehyde and formaldehyde resin manufacture, and use of some formaldehyde resin products (mainly wood products). Due to the limited amount of monitoring data for other use scenarios, all data are presented in tables 15.1 to 15.8 with information on number of samples, exposure duration, sampling and analytical methods, results, and relevant comments. However, it is noted that there are limitations for some data presented, for example, the reported single sample results are likely to involve a large coefficient of variation.”

CHAPTER 16-17 CRITICAL EFFECTS & RISK CHARACTERISATION

110 Variation requested by Orica

Section 16.4.2, page 173, paragraph 1, line 5: Insert: “.....observed that the predicted formaldehyde....”

Decision

Variation supported.

111 Variation requested by Orica

Section 16.4.4, insert the IPCS (2002) statement: “measures taken to prevent sensory irritation in human populations are sufficiently protective with respect to carcinogenic potential” because sensory irritation occurs at lower concentration than that producing histological damage to the nose.

Decision

Proposed text not supported. For clarity and to provide more information on the models, the section has been revised and will read as follows:

“16.4.4 Carcinogenicity

The exposure data for the epidemiology studies are such that they are not sufficient to establish a dose-response relationship for the purposes of cancer risk characterisation. A number of risk estimation models have been used to predict human cancer risks from inhalation exposure to formaldehyde, based on the nasal tumour response in rats. Models include: fifth-order multistage model (US EPA, 1987), third-order multistage model (US EPA, 1991), benchmark dose model (Schlosser et al, 2003) and biologically based model (Conolly et al, 2004). Based on these models, upper bound risk estimates at 0.1 ppm formaldehyde exposure range from 1.3×10^{-3} to 5.8×10^{-7} (Schlosser et al, 2003).

It is considered that the biologically-based 2-stage clonal growth model (Conolly et al, 2004), that incorporates mechanistic data on the proposed mode of action of tumour formation in rats, provides a better estimate of the actual risk of nasal cancer over the default approach of applying standard 10 x 10 default assumptions. The model offers the potential to decrease the uncertainties inherent in the extrapolation of data, both across species (e.g. rat to human) and from high experimental bioassay concentrations to those relevant to human exposure.

The model incorporates data on normal growth curves for rats and humans, cell cycle times, and cells at risk in the different regions of the respiratory tract. Species variations in dosimetry are taken into account by computational fluid dynamic models of the rat and human noses to predict regional formaldehyde doses (flux). Lower respiratory tract flux was predicted in humans in this model using a single path mode for the nasal, oral and lung airways. The details of the 2-stage clonal growth model and selection of various parameters can be found in Conolly et al., 2004 and are summarised in Appendix 14.

Although the mechanism of action is not well understood for nasal tumour formation in rats, regenerative cell proliferation associated with cytotoxicity appears to be an obligatory step in the induction of cancer by formaldehyde. In contrast, the probability of mutation resulting from DNA protein cross-linking (DPX) is unknown. However, in this model formaldehyde is assumed to act as a direct mutagen, with the effect considered proportional to the estimated tissue concentration of DPX. This is despite the fact that animal studies are suggestive of a threshold effect for carcinogenicity. Thus, this component of the model provides a conservative and cautionary element in recognition of a lack of a fully elucidated mechanism of action.

Maximum likelihood estimate methods were used to fit the clonal growth model to cancer incidence data. A number of sensitivity analyses were run to determine the significance of specific modelling assumptions (i.e. the probability of mutation per cell division and the growth advantage for preneoplastic cells). Age-adjusted data on the incidence of lung cancers in humans were used to calibrate the human model for background tumour incidence.

Estimates of the human carcinogenic risk for occupational and public exposures (for non-smokers) using the clonal growth model are presented in Table 16.1. The clonal growth model predicts that for 40-year occupational exposure to 0.3 ppm formaldehyde (the NICNAS recommended occupational exposure standard), the estimated additional risk for respiratory tract cancers is approximately 2 in 10 million. While at 1 ppm (the current occupational exposure standard) the estimated additional risk is approximately 50 in a million. Similarly for public exposure, at the recommended indoor air guidance value (80 ppb), the estimated additional risk is approximately 3 in 10 million.

Table 16.1: Predicted human additional risk of respiratory tract cancer due to public and occupational exposures to formaldehyde (for non-smokers)

Formaldehyde Exposure Concentration (ppm)	Predicted Additional Risk	
	Public ¹	Occupational ²
0.001	2.94×10^{-9} (≈ 3 in 1 billion)	Simulation not done
0.02	6.02×10^{-8} (≈ 6 in 100 million)	1.86×10^{-8} (≈ 2 in 100 million)
0.04	1.23×10^{-7} (≈ 1 in 10 million)	2.70×10^{-8} (≈ 3 in 100 million)
0.06	1.9×10^{-7} (≈ 2 in 10 million)	3.58×10^{-8} (≈ 4 in 100 million)
0.08	2.6×10^{-7} (≈ 3 in 10 million)	4.50×10^{-8} (≈ 4 in 100 million)
0.10	3.3×10^{-7} (≈ 3 in 10 million)	5.48×10^{-8} (≈ 5 in 100 million)
0.30	1.25×10^{-6} (≈ 1 in 1 million)	1.79×10^{-7} (≈ 2 in 10 million)
0.50	2.42×10^{-6} (≈ 2 in 1 million)	3.38×10^{-7} (≈ 3 in 10 million)
0.60	3.09×10^{-6} (≈ 3 in 1 million)	4.56×10^{-7} (≈ 5 in 10 million)
0.70	4.86×10^{-6} (≈ 5 in 1 million)	2.20×10^{-6} (≈ 2 in 1 million)
1.00	3.29×10^{-5} (≈ 33 in 1 million)	4.92×10^{-5} (≈ 50 in 1 million)

¹80 year lifetime continuous exposure at indicated ppm.

²80 year lifetime continuous exposure to a background environmental background level of 4 ppb with 40 years occupational exposure (8hr/day, 5 days/week) at indicated ppm beginning at age 18 years, with a “light working” breathing pattern.

Due to public concern of childhood chemical exposure and cancers, together with the findings of relatively high levels of formaldehyde in mobile homes and relocatable buildings, a worst-case scenario risk estimation incorporating higher exposures during childhood, has been conducted using the CIIT modelling (Appendix 15). The worst-case scenario was identified to be children who live in mobile homes and spend all their schooling time in relocatable classrooms up to 17 years of age. The details of the worst-case scenario exposure levels, respiratory ventilation rate at different activity levels and other parameters used in the modelling are in Appendix 15. The predicted additional risk of respiratory tract cancer for a full 80-year lifetime, including childhood exposure to formaldehyde under the worst-case scenario is 0.45 in a million.

The clonal growth model (Conolly et al., 2004) is considered to provide the best estimates of cancer risk. However, it is noted that this model predicts substantially lower cancer risk than other models. This is attributed to the maximised use of mechanistic data in the clonal growth model, including the incorporation of data on normal growth curves for rats and humans, cell cycle times and cells at risk in different regions of the respiratory tract (i.e. regional formaldehyde flux). NICNAS notes that CIIT and other regulatory authorities are reviewing the 2-stage clonal growth model and developing other risk estimates for cancer. These risk estimates when available, will be considered along with any new significant epidemiological data as an ongoing process of re-evaluation of cancer risk as part of secondary notification activities (see chapter 19).

112 Variation requested by Orica

Page 173, section 16.4.4, include some background information relating to the development of the CIIT modelling as done in the IPCS report (2002) to provide greater confidence for the reader regarding the acceptability of the modelling approach.

Decision

Variation supported. The Appendix 4 of the IPCS report (2002) which provided details on the CIIT modelling will be added as a new Appendix to the draft PEC report.

113 Variation requested by Orica

Section 16.4.4,

- i) page 173, 2nd paragraph, line 1: amend as “Although the molecular mechanism of action”
- ii) Page 174, paragraph 2. line 1: amend as “For default modelling of additional cancer risk from formaldehyde exposures in Australia, maximum likelihood estimate methods ...”
- iii) Page 174, paragraph 4, line 1: amend as “Maximum likelihood estimates of the additional carcinogenic risk- iv) Page 175, Table heading: amend as “Predicted maximum human additional- v) Table 16.1: Please provide an explanation in the table footnotes on the significance of bolded entries in the table.

Decision

Variations i), iii) and iv) supported.
Variation ii) not supported.
Variation v) supported but text no longer bolded.

Comment

Variation request ii) – the modelling was not done for “Australian” exposure.

114 Variation requested by Orica, QCU, AMWU, LHMU, ACTU, VTHC

Orica:

Section 16.4.4, page 175, last paragraph. Additional information is needed for the benchmark dose (BMD) modelling, otherwise delete the paragraph.

QCU, AMWU, LHMU, ACTU, VTHC:

The draft PEC report be varied to ensure that other risk estimate models are considered, and if rejected, explain the perceived inadequacies of the other models, so that the reasoning for the use of such the CIIT model be justified.

Decision

Variation supported and the draft PEC report will be amended as follows:

“16.4.4 Carcinogenicity

The exposure data for the epidemiology studies are such that they are not sufficient to establish a dose-response relationship for the purposes of cancer risk characterisation. A number of risk estimation models have been used to predict human cancer risks from inhalation exposure to formaldehyde, based on the nasal tumour response in rats. Models include: fifth-order multistage model (US EPA, 1987), third-order multistage model (US EPA 1991), benchmark dose model (Schlosser et al, 2003) and biologically based model (Conolly et al, 2004). Based on these models, upper bound risk estimates at 0.1 ppm formaldehyde exposure range from 1.3×10^{-3} to 5.8×10^{-7} (Schlosser et al, 2003).

It is considered that the biologically-based 2-stage clonal growth model (Conolly et al, 2004), that incorporates mechanistic data on the proposed mode of action of tumour formation in rats, provides a better estimate of the actual risk of nasal cancer over the default approach of applying standard 10 x 10 default assumptions. The model offers the potential to decrease the uncertainties inherent in the extrapolation of data, both across species (e.g. rat to human) and from high experimental bioassay concentrations to those relevant to human exposure.

The model incorporates data on normal growth curves for rats and humans, cell cycle times, and cells at risk in the different regions of the respiratory tract. Species variations in dosimetry are taken into account by computational fluid dynamic models of the rat and human noses to predict regional formaldehyde doses (flux). Lower respiratory tract flux was predicted in humans in this model using a single path mode for the nasal, oral and lung airways. The details of the 2-stage clonal growth model and selection of various parameters can be found in Conolly et al., 2004 and are summarised in Appendix 14.

Although the mechanism of action is not well understood for nasal tumour formation in rats, regenerative cell proliferation associated with cytotoxicity appears to be an obligatory step in the induction of cancer by formaldehyde. In contrast, the probability of mutation resulting from DNA protein cross-linking (DPX) is unknown. However, in this model formaldehyde is assumed to act as a direct mutagen, with the effect considered proportional to the estimated tissue concentration of DPX. This is despite the fact that animal studies are suggestive of a threshold effect for carcinogenicity. Thus, this element of the model provides a conservative and cautionary element in recognition of a lack of a fully elucidated mechanism of action.

Maximum likelihood estimate methods were used to fit the clonal growth model to cancer incidence data. A number of sensitivity analyses were run to determine the significance of specific modelling assumptions (i.e. the probability of mutation per cell division and the growth advantage for preneoplastic cells). Age-adjusted data on the incidence of lung cancers in humans were used to calibrate the human model for background tumour incidence.

Estimates of the human carcinogenic risk for occupational and public exposures (for non-smokers) using the clonal growth model are presented in Table 16.1. The clonal growth model predicts that for 40-year occupational exposure to 0.3 ppm formaldehyde (the NICNAS recommended occupational exposure standard), the estimated additional risk for respiratory tract cancers is approximately 2 in 10 million.

While at 1 ppm (the current occupational exposure standard) the estimated additional risk is approximately 50 in a million. Similarly for public exposure, at the recommended indoor air guidance value (0.08 ppb), the estimated additional risk is approximately 3 in 10 million.

Table 16.1: Predicted human additional risk of respiratory tract cancer due to public and occupational exposures to formaldehyde (for non-smokers)

Formaldehyde Exposure Concentration (ppm)	Predicted Additional Risk	
	Public ¹	Occupational ²
0.001	2.94×10^{-9} (\approx 3 in 1 billion)	Simulation not done
0.02	6.02×10^{-8} (\approx 6 in 100 million)	1.86×10^{-8} (\approx 2 in 100 million)
0.04	1.23×10^{-7} (\approx 1 in 10 million)	2.70×10^{-8} (\approx 3 in 100 million)
0.06	1.9×10^{-7} (\approx 2 in 10 million)	3.58×10^{-8} (\approx 4 in 100 million)
0.08	2.6×10^{-7} (\approx 3 in 10 million)	4.50×10^{-8} (\approx 4 in 100 million)
0.10	3.3×10^{-7} (\approx 3 in 10 million)	5.48×10^{-8} (\approx 5 in 100 million)
0.30	1.25×10^{-6} (\approx 1 in 1 million)	1.79×10^{-7} (\approx 2 in 10 million)
0.50	2.42×10^{-6} (\approx 2 in 1 million)	3.38×10^{-7} (\approx 3 in 10 million)
0.60	3.09×10^{-6} (\approx 3 in 1 million)	4.56×10^{-7} (\approx 5 in 10 million)
0.70	4.86×10^{-6} (\approx 5 in 1 million)	2.20×10^{-6} (\approx 2 in 1 million)
1.00	3.29×10^{-5} (\approx 33 in 1 million)	4.92×10^{-5} (\approx 50 in 1 million)

¹80 year lifetime continuous exposure at indicated ppm.

²80 year lifetime continuous exposure to a background environmental background level of 4 ppb with 40 years occupational exposure (8hr/day, 5 days/week) at indicated ppm beginning at age 18 years, with a “light working” breathing pattern.

Due to public concern of childhood chemical exposure and cancers, together with the findings of relatively high levels of formaldehyde in mobile homes and relocatable buildings, a worst-case scenario risk estimation incorporating higher exposures during childhood, has been conducted using the CIIT modelling (Appendix 15). The worst-case scenario was identified to be children who live in mobile homes and spend all their schooling time in relocatable classrooms up to 17 years of age. The details of the worst-case scenario exposure levels, respiratory ventilation rate at different activity levels and other parameters used in the modelling are in Appendix 15. The predicted additional risk of respiratory tract cancer for a full 80-year lifetime, including childhood exposure to formaldehyde under the worst-case scenario is 0.45 in a million.

The clonal growth model (Conolly et al., 2004) is considered to provide the best estimates of cancer risk. However, it is noted that this model predicts substantially lower cancer risk than other models. This is attributed to the maximised use of mechanistic data in the clonal growth model, including the incorporation of data on normal growth curves for rats and humans, cell cycle times and cells at risk in different regions of the respiratory tract (i.e. regional formaldehyde flux). NICNAS notes that CIIT and other regulatory authorities are reviewing the 2-stage clonal growth model and developing other risk estimates for cancer. These risk estimates when available, will be considered along with any new significant epidemiological

data as an ongoing process of re-evaluation of cancer risk as part of secondary notification activities (see chapter 19).

115 Variation requested by NSW DEC

Page 177, 4th paragraph, 2nd sentence reads “Data from Italy showed high mean concentrations of 3.9ppb”. It is not clear why a value of 3.9ppb would be classed as a “high” value given that it is so far below the levels expected to cause effects or recommended indoor and outdoor air quality guideline values. The term high should be removed from the sentence.

Decision

Variation supported.

116 Variation requested by NSW DEC

Page 178, 3rd paragraph, last sentence, should 200ML be changed to 200 fold?

Decision

Variation supported. The text for this sentence will be amended as follows: “Derivation of a PEC from estimated concentration (<20 mg/L) in trade waste entering the sewer is not possible. However, the concentration will be significantly reduced through dilution in the sewer.”

117 Variation requested by QLD DIR

Page 180, 1st paragraph, section 17.2.1 ‘Public exposure’, reference should be provided for the statement “The modelled values are generally in agreement with measured values”.

Decision

Variation supported and reference ‘(details in section 13.1.6)’ will be added.

118 Variation requested by AWPA/PAA

Page 180, 1st paragraph, add following text before the last sentence: “Assumptions required for modelling, result in some uncertainty in the estimated exposure levels but indicate locations where actual monitoring of formaldehyde levels should be undertaken.”

Decision

Variation supported. Following text will be added at the end of this paragraph: “Assumptions required for modelling, result in some uncertainty in the estimated exposure levels but indicate locations where actual monitoring of formaldehyde levels or site specific modeling should be undertaken.”

Note: some boundary data on formaldehyde levels around wood manufacturing plants were provided by the AWPA/PAA during public comment stage. The data will be added in the draft PEC report.

119 Variation requested by AWPAA/PAA

Page 180, Section 17.2.2, amend the text as follows:

“The critical health effects for the characterisation of public health risk associated with the inhalation of formaldehyde in the environment are sensory irritation, and carcinogenicity.”

Decision

Variation partially supported. Text will be amended as follows:

“The critical health effects for the characterisation of public health risk are skin sensitisation following dermal exposure to formaldehyde solutions and sensory irritation and carcinogenicity via inhalation exposure to formaldehyde.”

Comment

The applicants correctly identified that skin sensitisation is not a result of inhalation exposure and should be deleted. However skin sensitisation following dermal contact with formaldehyde solutions is a critical health effect and text will be amended.

120 Variation requested by Orica, AWPAA/PAA

Page 182, table 17.1, ‘Sensory irritation’, replace “...and people living near wood and paper industry facilities that are larger emitters of formaldehyde” with “Modelled maximum 24 hr average concentrations of formaldehyde at the assumed boundary of the largest wood & paper facility emitter of formaldehyde appeared high and more information is required to obtain better estimates.”

Decision

Variation supported. The text will be amended as:

“Modelled maximum 24 hr average concentrations of formaldehyde at the assumed boundary of the largest wood and paper facility emitters of formaldehyde were above 40 ppb, the NEPM investigation level. More information is required such as monitoring or site specific modelling, to reduce the uncertainties.”

Wherever relevant in the draft PEC report, reference to risk of sensory irritation to the residents living close to these types of facilities will be deleted.

121 Variation requested by AWPAA/PAA

Page 184, 2nd paragraph,

i) 2nd and 3rd sentence, replace with:

“...However, air formaldehyde levels may be higher when formaldehyde based resins are heated due to the volatility of the free formaldehyde present. When handling formaldehyde based resins workers should consult the MSDS and the use the appropriate work place procedures and controls.”

ii) delete the last sentence.

Decision

Variations i) and ii) not supported.

Comment

Variation i) – Formaldehyde polymers or products containing formaldehyde polymers can decompose to release significant amounts of formaldehyde when overheated (refer to section 5.2 of the draft PEC report).

Variation ii) - the applications of formaldehyde based resins in non-wood products uses are discussed in the draft PEC report (page 150, 1st paragraph).

122 Variation requested by FCI

Page 186, section 17.4 delete:

‘Epidemiology data studying the association between formaldehyde exposure and leukaemia and possible mode of action.’

Decision

Variation not supported.

Comment

Some epidemiology studies have shown an increased incidence of leukaemia. These findings cannot be dismissed and therefore further work should be conducted to determine the significance of these findings.

123 Variation requested by Orica

Section 17.2.3, and 17.3.3, uncertainty analysis for public and occupational health need to be discussed further following the requirements of Australian enHealth (2002) guidelines.

Decision

Variation not supported.

Comment

A qualitative analysis of uncertainty is provided in reasonable detail in the draft PEC report including the major uncertainties for the risk characterisation. There is insufficient data to enable a quantitative analysis to be conducted.

124 Variation requested by Orica

Request the term “low” be replaced by “negligible” wherever the calculated cancer risks are equal or less than one in a million. Several references were given to support this request, including NZ MfE and MoH; California, NHMRC; HSE and US EPA.

Decision

Variation not supported.

Comment

Setting an acceptable level of risk is a policy decision. There is no policy statement, nationally or internationally, on what is an acceptable level of cancer risk.

NICNAS has classified formaldehyde as a cancer hazard and therefore there is a need to manage potential cancer risks. The current risk estimates are based on modelled data, using the CIIT model, and are not based on actual human cancer incidences. Although these estimates are considered to provide a better estimate of actual risk than, for example, the default approach of low-dose linear extrapolation, NICNAS notes that other models have estimated higher risks (from approximately 1×10^{-3} to 1×10^{-5}). Therefore, although NICNAS considers the risk of cancer to be low, we do not consider that the strength of data nor the degree of certainty is sufficient to conclude that the cancer risk is negligible.

CHAPTER 18 RISK MANAGEMENT

125 Variation requested by FCI

Page 204, section 18.2.5, 'Indoor Air', Amend the indoor air guidance value from 80 ppb to 300 ppb based on the requested NOEL of 0.75 to 1 ppm for sensory irritation and a national research council (NRC) document on guidance levels for selected submarine contaminants which concluded that 'a concentration of 0.3 ppm is unlikely to result in discomfort in the submariner population.'

Several consequential variation were also requested.

Decision

Variation not supported.

Comment

The NICNAS proposed indoor air guidance value is derived using the WHO approach for deriving guidance values for health based exposure limits considering interspecies variability to account for toxicodynamic and toxicokinetic differences between individuals.

In addition, sensory irritation relies on subjective reporting of symptoms and therefore it is difficult to identify a definitive NOEL. In addition, the sensory irritation data for formaldehyde at low doses are not robust. The chamber studies which have indicated eye irritation effects (the most sensitive effect) at or below 0.5 ppm are Anderson and Molhave (1983) and Bender et al (1983). The Kulle studies report no eye irritation at 0.5 ppm, the only dose tested below 1.0 ppm. The other chamber studies have either not tested at concentrations below 1.0 ppm or do not provide data for the individual exposure concentrations. It is acknowledged that the data are limited and all studies have limitations. The sensory irritation effects at the lower doses should not be dismissed because a significant number of controls also report symptoms. Based on the weight of evidence, it is concluded that there are some individuals who will experience sensory irritation at 0.5 ppm. Therefore, 0.5 ppm should be considered a LOEL and not an NOEL.

NICNAS has used a cautionary approach and appropriate uncertainty factors based on the evidence of mode of action and available data for sensory irritation. In addition, we note that this level will also provide adequate risk management for nasal cancers.

Therefore, NICNAS does not support a NOEL at or above 0.5 ppm or a LOEL higher than 0.5 ppm.

Several references to 'no reliable NOEL' will be deleted because this statement can be seen as misleading. It is not that there is no NOEL, but a NOEL is not easily defined for a subjective effect.

126 Variation requested by Orica

Page 206, paragraph 3, lines 15 –16, Replace "...based on a study of eye irritation by Paustenbach et al (1997)..." with: "...based on an extensive review by Paustenbach et al. (1997) of the literature dealing with formaldehyde induced sensory irritation."

Decision

Variation supported.

APPENDIX 7 EASE MODELLING FOR FILM PROCESSING

127 Variation requested by Orica

Request the uncertainties in the EASE modelling to be fully discussed and significantly more detail be provided on the EASE modelling in Appendix 7.

Decision

Variation partially supported. A brief description of the EASE model will be added.

Comment

The details of all parameters used in the modelling for film processing are provided in Appendix 7. In addition, the possibility of overestimate of exposure using the EASE model is acknowledged in section 15.2.

APPENDIX 9 SAMPLE MSDS

128 Variation requested by Haztech Environmental

A sample MSDS for the most typically traded product (Formaldehyde 37%, Methanol 7%) should be created and Notes made for how different Methanol concentrations will change the MSDS be added following this MSDS. Several related variations for including information on methanol in the MSDS were also included.

Decision

Variation partially supported. A paragraph will be added under the heading of the Appendix 9:

"It is understood that stabilisers, such as methanol and various amine derivatives, are added to formaldehyde solutions to reduce the intrinsic polymerisation of formaldehyde. To avoid complications introduced by the additive, this sample MSDS only presents information on a solution containing 37% formaldehyde. The

information used in this sample MSDS is from the findings of this assessment and reliable sources. Also, where relevant, only guidance information (text in italic) is provided. Industry is required to create accurate text accordingly in consultation with relevant documents and/or organisations.”

All consequential variation requests will be covered by the above statement.

Comment

It is not NICNAS’s practice to provide sample MSDS for mixtures. Concentrations of methanol in formaldehyde solutions vary, so do the risk and safety phrases. Also other additives may be added. Therefore, to avoid complications introduced by the additive, this sample MSDS only presents information on 37% formaldehyde solution.

129 Variation requested by Haztech Environmental

a) Page 255, the title of the sample MSDS should be for formalin or formaldehyde solution, 37%, not formalin 37%.

Decision

Variation supported and will be amended as “Formaldehyde solution, 37%”.

b) Page 256, Section 4, ‘First Aid Measures’,

i) The Note about contact lenses should be in Section 7 ‘Handling and Storage’ or Section 8 ‘Personal Protection’;

ii) the ‘Advice to the Doctor’, suggest to change to “There is no specific antidote for Formaldehyde poisoning. Treat symptomatically and supportively.”

Decision

Variation i) supported. The Note about contact lenses will be moved to Section 8 ‘Personal Protection’.

Variation ii) supported.

c) Page 258, section 7, ‘Handling and Storage’, 2nd box ‘Conditions for safe storage, including any incompatibilities’, there is no clear advice to "Store in accordance with Dangerous Goods (Storage & Handling) Regulations and AS/NZS 3780 The Storage & Handling of Corrosive Substances. Also classified as C1 Combustible Liquid which should be stored in accordance with AS 1940 Storage & Handling of Flammable & Combustible Liquids."

Decision

Variation supported. Due to the complexity regarding flammability and corrosiveness of formaldehyde solutions (see Table 18.8 in the draft PEC report for details), this section will be replaced with following guidance information (text in *italic*):

“Formaldehyde meets the criteria for a dangerous good so national storage and handling regulations for dangerous goods are applicable. Storage and handling requirements are described in the OASCC National Standard for the Storage and Handling of Workplace Dangerous Goods and OASCC National Code of Practice for the Storage and Handling of Workplace Dangerous Goods.”

d) Page 258, section 8, 'Exposure Controls/Personal Protection', glove types are not provided.

Decision

Variation not supported but noted. This section will be replaced with following guidance information (text in *italic*):

"Please refer to NICNAS Safety Information Sheet on formaldehyde, relevant Australian Standards and consult with manufacturers of PPE for accurate information."

Comment

It is not customary for NICNAS to include for recommendations on appropriate glove types, as the choice of type of PPE needs to take a number of factors into consideration such as permeability of other ingredients in the product. However, this issue will be covered in the Safety Information Sheets to be developed. Relevant organisations will be consulted in this process.

e) Page 259, Section 10, 'Stability and Reactivity', More information on its stability is needed to emphasize issues of precipitation at low temperatures, air oxidation to Formic Acid, and changing to Paraformaldehyde. Suggested wording: "On standing, especially in cold may become cloudy and on exposure to very low temperatures a precipitate of Paraformaldehyde is formed. In the air it slowly oxidizes to Formic Acid. When evaporated, some Formaldehyde escapes, but most of it is changed to Paraformaldehyde."

Decision

Variation supported and the text will be amended as: "Formalin may become cloudy on standing, especially at cool temperatures, and form paraformaldehyde at very low temperatures. Formaldehyde slowly oxidizes in air to formic acid and is sensitive to light and is easily hydrated and polymerised if not stabilised."

f) Page 260, section 11, 'Toxicological Information':

- i) Toxicity data LD50 and LC50 is missing for formaldehyde.
- ii) A brief explanation about its carcinogenic effects is needed.

Decision

Variation i) supported.

Variation ii) not supported.

Comment

Variation ii) - Information on health effects in sample MSDS should be as concise as possible and in plain English. NICNAS would not wish to dilute the effect of the warning 'may cause cancer by inhalation' with extensive technical text.

g) Page 260, section 12, 'Ecological Information', needs more information to be useful.

Decision

Variation supported.

h) Page 260, section 13, 'Disposal Considerations', needs more information to be useful.

Decision

Variation supported.

i) Page 261, section 14, 'Transport Information', the information should be done just for 37% formaldehyde solution.

Decision

Variation supported.

j) Sample label should be provided.

Decision

Variation not supported.

Comment

Usually product MSDS contain more detailed information that is required on product labels by the OASCC Labelling Code. Therefore, industry can refer to the sample MSDS for information when preparing product labels.

130 Variation requested by Merck

a) Page 255, section 2,

i) Word missing, R43 should be 'May cause sensitisation by skin contact';

ii) R45 should read R49;

iii) delete the words '(Carcinogen, category 2)';

iv) safety phrase, S13 should be 'Keep away from...'

Decision

Variations i) to iv) supported.

b) page 258, section 8, specific types of PPE should be provided.

Decision

Variation not supported but noted.

Comment

It is not customary for NICNAS to include for recommendations on appropriate glove types, as the choice of type of PPE needs to take a number of factors into consideration such as permeability of other ingredients in the product. However, this issue will be covered in the Safety Information Sheets to be developed. Relevant organisations will be consulted in this process.

APPENDIX 13 PROPOSED OCCUPATIONAL EXPOSURE STANDARD

Attachment 2

131 Variation requested by Orica

Under sub-heading 'Basis for setting the limit',

i) Delete 2nd sentence and replace with:

“The dose response characteristics of formaldehyde sensory irritation and subjective nature of the effect do not enable an unconditional population based no observed effect level to be defined.”

Decision

Variation partially supported. The text will be amended as follows:

“Although formaldehyde is a known upper respiratory tract irritant in humans, the limitations of the available data and subjective nature of sensory irritation do not allow identification of a definitive no observed effect level (NOEL).”

ii) Line 9 -10: Delete sentence starting with “Therefore, the lowest.....” and replace with-

“Therefore for most of the population 0.5 ppm represents a no effect level for sensory irritation of the eye and upper respiratory tract. However the data do not allow it to be categorically stated that some people will not sense formaldehyde at lower concentrations.”

Decision

Variation not supported.

Comment

Sensory irritation relies on subjective reporting of symptoms and therefore it is difficult to identify a definitive NOEL. In addition, the sensory irritation data for formaldehyde at low doses are not robust. The chamber studies which have indicated eye irritation effects (the most sensitive effect) at or below 0.5 ppm are Anderson and Molhave (1983) and Bender et al (1983). The Kulle studies report no eye irritation at 0.5 ppm, the only dose tested below 1.0 ppm. The other chamber studies have either not tested at concentrations below 1.0 ppm or do not provide data for the individual exposure concentrations. It is acknowledged that the data are limited and all studies have limitations. The sensory irritation effects at the lower doses should not be dismissed because a significant number of controls also report symptoms. Based on the weight of evidence, it is concluded that there are some individuals who will experience sensory irritation at 0.5 ppm. Therefore, 0.5 ppm should be considered a LOEL and not an NOEL.

NICNAS has used a cautionary approach and appropriate uncertainty factors based on the evidence of mode of action and available data for sensory irritation. In addition, we note that this level will also provide adequate risk management for nasal cancers.

Therefore, NICNAS does not support a NOEL at or above 0.5 ppm or a LOEL higher than 0.5 ppm.

iii) The rationale for choosing 0.3 ppm (8 hr TWA) and 0.6 ppm (STEL) for the proposed occupational exposure standard is not clear. Delete last sentence of paragraph 1 plus paragraph 2-3 and replace with:

“In order that the majority of workers are not inconvenienced or unduly discomforted by formaldehyde induced sensory irritation the recommended exposure standard should be a concentration that is a little lower, or ‘at or about’ the no effect level identified for sensory irritation from chamber studies with volunteers. This will account for uncertainty in the NOEL and variability in worker susceptibility to sensory irritation by formaldehyde. Although the sensory irritation is associated with only relatively mild effects the fact that formaldehyde is an established animal carcinogen (producing tumours in the nasal cavity with high exposures) and a Category 2 human carcinogen also needs to be taken into consideration when establishing the exposure standard. Current understanding of the carcinogenic mode of action of formaldehyde from many experimental studies indicates hyperplasia secondary to cytotoxicity is an obligatory step in the carcinogenic cascade. Hence measures taken to prevent significant sensory irritation will also be protective with respect to carcinogenic potential because sensory irritation occurs at lower concentrations than those producing histological damage to the nose (IPCS, 2002). For these reasons the recommended exposure standard is 0.3 ppm TWA and 0.6 ppm STEL. At the recommended TWA the predicted carcinogenic risk using state of art biologically motivated modelling is less than one in a million and therefore considered negligible. Furthermore the recommended exposure standards are consistent with best practice overseas and from industry information submitted for this report appear technically achievable in most Australian workplaces. It is also noted that because formaldehyde is a Category 2 human carcinogen exposures should be maintained as low as practicable and the standards have been recommended with this in mind.”

Decision

Variation partially supported. The last sentence of paragraph 1 remains and paragraph 2-3 are replaced with:

“In order to protect the majority of workers from sensory irritation, the recommended exposure standard should be a concentration that is a lower than the LOEL identified. As this is a reversible effect and effects are generally mild at 0.5 ppm, the standard should be slightly lower than the LOEL. For these reasons the recommended exposure standard is 0.3 ppm TWA and 0.6 ppm STEL. At this level, the nasal cancer risk can be also managed. Furthermore the recommended exposure standards are consistent with best practice overseas and from industry information submitted for this report appear technically achievable in most Australian workplaces.”

132 Variation requested by Orica

Under sub-heading ‘Toxicokinetics’,

i) replace 1st paragraph with: “Owing to its high water solubility, inhaled formaldehyde is readily absorbed in the regions of the upper respiratory tract with which it comes into contact. Its rapid metabolism and high reactivity with biological

macromolecules confine formaldehyde to tissues of first contact and blood concentrations do not increase.”

ii) Change line 1 of paragraph 2: “The half - life is about 1 to ...”

iii) 3rd paragraph, line 3: The information of 40% expired as CO₂ is different from the information in Section 9, there it is stated that ¹⁴C derived from ¹⁴C-formaldehyde was expired. Please correct the information at line 3 of paragraph 3.

Decision

Variations i) and ii) not supported.

Variation iii) supported. The 2nd and 3rd sentence will be deleted.

Comment

Variation i) - This paragraph discusses absorption only. The metabolism of formaldehyde is discussed in 2nd paragraph.

Variation ii) – the rapid metabolism of formaldehyde remains appropriately addressed.

133 Variation requested by Orica

Several request for variations under sub-heading ‘Health Effects’ are all consequential to the comments on the main body of the draft PEC report.

Decision

This section will be amended consistent with agreed changes to the main body of the draft PEC report.

APPENDIX 15 WORST-CASE SCENARIO CANCER RISK ESTIMATION

134 Variation requested by Orica

Not all of the information for the worst case modelling undertaken by Dr Conolly appears to be in Appendix 15.

Decision

Variation supported. For clarity, Appendix 4 of the IPCS (2002) report will be included in the draft PEC report as an appendix.

REFERENCES

135 Variation requested by Department of Health, WA

i) Reference to Conolly (2005) on page 175 should refer to Appendix 15 and delete Conolly (2005) from the reference list.

Decision

Variation supported.

- ii) Appendix 15, page 279 – reference should be Conolly et al, (2004)

Decision

Variation supported.

- iii) References listed as ‘in press’ should be updated with the full reference if they have been published. In reference list, amend spelling, in Collins and Linekar (2004) to Lineker.

Decision

Variation supported.

NICNAS Response to Comments (rather than variation requests)

1 Comment from QCU, VTHC, AMWU, ACTU, LHMU

In 'Recommendations for Environmental Protection', the recommendations are not strong enough in terms of planning permits etc. There is nothing in these recommendations to any state EPA or local government authority.

NICNAS response

This issue principally arises because of the current lack of a nationally consistent environmental protection framework. This is being addressed by EPHC development of a national management framework for chemicals.

2 Comment from DPK Australia Pty Ltd.

The company has started using a new product containing formaldehyde resin that has <0.5% free formaldehyde in textile treatment.

NICNAS response

The comment is noted. This issue is already addressed in the draft PEC report (page 31-32, under subheading 'Textile treatment').

3 Comment from QLD DIR

Page 77, section 11.3.1, further to the data in Table 11.2 provided by the Occupational Dermatology Research & Education Centre (ODREC) an email report, received from the ODREC in Victoria on 26 September 2005, indicates that there were no formalin diagnosed reactions from any embalmers or mortuary workers in their database of 2,500 patients over the past 12 years.

NICNAS response

NICNAS has contacted ODREC and been advised that Table 11.2 is compiled of patients seen in an Occupational Dermatology Clinic over a 10 year period. The patients are referred from dermatologists, occupational physicians/company medical officers, Allergists, GPs, occupational health nurses, OHS personnel, insurance companies & company managers. All patients are thought to have a work-related skin problem when they are referred. The biggest occupational group with allergy to formalin has been registered nurses. No any embalmers or mortuary workers with skin problems were referred to the clinic during that period. It could be due to that workers in some industry groups see skin problems as 'part of the job'. Direct communication with embalmers & mortuary workers may reveal the presence of skin problems.

4 Comment from QCU, AMWU, LHMU, ACTU, VTHC

The QCU / WHC strongly support the listing of formaldehyde as a skin sensitiser and does not support claims that there are thresholds for skin sensitisation that would be of any useful assistance in the workplace.

NICNAS response

The following text will replace the paragraph in section 16.4.3:

“Several animal and human studies (Marzulli & Maibach, 1974; Jordan et al, 1979; Hilton et al, 1996; Hilton et al, 1998) have been conducted to induce and/or elicit a skin sensitisation response for the purpose of hazard identification. These studies were conducted at doses to elicit a response and not designed to identify a threshold.

There is growing consensus that thresholds can be identified for skin sensitisers [Kimber et al., 1999; 2001; Boukhman & Maibach, 2001; EU Working Group on Sensitisation (ECBI/13/02 Add.1), http://ecb.jrc.it/classlab/1302a1_Report.doc]. At present, which tests are the most appropriate to identify a threshold have not been agreed upon.

Work is also underway to categorise skin sensitisers according to their potency. For example, the EU Expert Group on Sensitisation (ECBI/81/02, 2002, http://ecb.jrc.it/classlab/8102_Sensitisation_1102_report.doc.) proposed three categories of skin sensitisers (extreme, strong, moderate) based on a range of sensitisation tests (LLNA, Bueller, and human data). The Expert Group categorised formaldehyde as a strong skin sensitiser.”

5 Comment from NSW DEC

It is not clear whether exposure to formaldehyde during home renovations (particularly during sanding and cutting of particle board, plywood etc) or released from carpets has been appropriately evaluated.

NICNAS response

This is discussed in section 13.2, page 128, ‘Factors affecting indoor formaldehyde levels’.

6 Comment from QLD DIR

Page 145, Table 15.2a, the results for site 7, passive diffusion badges were among the methods used to collect 87 samples. The brand of badges used was not stated, however many such badges are not suitable for short term measurements and most that are have a detection range starting at 0.5 ppm, which is above most of the reported results. Accuracies are only about +/- 25% for these badges. Further assessment of this data is warranted before it is used for review of formaldehyde TWA exposure standards.

NICNAS response

These data were not used to set the occupational exposure standard.

7 Comment from QCU, AMWU, LHMU, ACTU, VTHC

The occupational exposure data based on industry reported monitoring data leaves the NICNAS Report open to suggestions of bias.

NICNAS response

Literature search on workplace monitoring data both in Australia and overseas have been conducted and the results are included in the draft PEC report (Table 15.1 to Table 15.8). Also some personal communication data in the tables are from state/territory OHS authorities.